EXHIBIT 1

AO 88A (Rev. 12/20) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Delaware

Apple Inc.
Plaintiff
v.
Masimo Corporation and Sound United, LLC
Defendant

Civil Action No. 22-cv-1378-MN-JLH

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Nonin Medical, Inc., 13700 1st Avenue N, Plymouth, MN 55441-5443
c/o Corporation Services Company, 2345 Rice St, Suite 230, Roseville, MN 55113
(Name of person to whom this subpoena is directed)

☑ Testimony: YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must promptly confer in good faith with the party serving this subpoena about the following matters, or those set forth in an attachment, and you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about these matters:

SEE ATTACHMENT A

Place:	Date and Time:
TransPerfect 150 S. 5th Street Minneapolis, MN 55402	08/08/2023 10:00 am

The deposition will be recorded by this method: Stenographically, audiotaped, and videotaped

☑ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

See Schedule A (attached). Documents to be produced on or before July 21, 2023, to:
Jamie Kringstein, Desmarais LLP, 230 Park Avenue, New York, NY 10169
jkringstein@desmaraisllp.com

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 07/06/2023

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

/s/ Jamie L. Kringstein
Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Plaintiff Apple Inc., who issues or requests this subpoena, are:

Jamie Kringstein | Desmarais LLP | 230 Park Ave., New York, NY 10169 | 212-808-2921 | jkringstein@desmaraisllp.com

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 22-cv-1378-MN-JLH

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

ATTACHMENT A

SCHEDULE A

DEFINITIONS

The following terms shall have the meanings set forth below whenever used in any Definition, Instruction, Request for Production, or Deposition Topic.

1. As used herein, the terms "Nonin," "You," or "Your" means Nonin Medical, Inc. and all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.

2. As used herein, "Apple" means Apple Inc., all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.

3. As used herein, "Masimo" means Masimo Corporation, Cercacor Laboratories, Inc., and all their predecessors (merged, acquired, or otherwise), successors, subsidiaries, parents, sisters, divisions, departments, partnerships, and affiliates thereof, and all of their officers, directors, principals, agents, employees, independent contractors working under their control, attorneys, and other persons acting on their behalf.

4. As used herein, "Masimo Asserted Patents" means U.S. Patent No. 10,687,743 ("the '743 Patent"), U.S. Patent No. 10,722,159 ("the '159 Patent"), U.S. Patent No. 8,190,223 ("the '223 Patent"), U.S. Patent No. 10,736,507 ("the '507 Patent"), and U.S. Patent No. 10,984,911 ("the '911 Patent").

5. As used herein, "Relevant Date" means September 20, 2012.

6. As used herein, "Exhibits" means Exhibits 1-3 attached hereto.

7. As used herein, "Blood Oxygen and Heart Rate Features" means the product feature(s) relating to monitoring, measuring, sensing, detecting, and/or obtaining blood oxygen (SpO2) and/or heart rate measurements, including all hardware, software, firmware, components, modules, applications, and devices involved in such features, that were made or sold before the Relevant Date.

8. As used herein, "Product" means any machine, manufacture, apparatus, device, system, process, service, method, or instrumentality which is designed to function together electrically, mechanically, chemically, or otherwise, to achieve a particular function or purpose, including those offered for sale, sold, imported, or under development.

9. As used herein, "Relevant Products" means (1) Nonin Onyx II Model 9650, (2) Nonin WristOx2 Model 3150, (3) Nonin 4100, (4) Nonin OEM II Module, (5) Nonin 8500M, (6) Nonin nVision, (7) Microsoft Health Vault, (8) the products described in Exhibits 1-3, (9) any Product made or sold by or for You having Blood Oxygen and Heart Rate Features before the Relevant Date, (10) any related Products or modules having Blood Oxygen and Heart Rate Features before the Relevant Date, and (11) any other software programs, applications, or modules that display Blood Oxygen or Heart Rate from the Relevant Products.

10. As used herein, "Source Code" means any human-readable programming language or format that defines software, firmware or integrated circuits, including but not limited to, computer code, scripts, assembly, binaries, object code, Register Transfer Level ("RTL") descriptions, VHDL, Verilog, and other Hardware Description Language ("HDL") formats.

11. The term "Third Party" means any person or entity other than You, Masimo, or Apple.

12. As used herein, the term "document" shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure and includes the original and every non-identical copy or reproduction in Your possession, custody, or control, and further is used in a broad sense to refer to any electronically stored information ("ESI") or any tangible object or thing that contains, conveys, or records information.

13. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

14. As used herein, "person" means any natural person or any business, legal, or governmental entity or association.

15. As used herein, "include" and "including" shall be construed to mean "without limitation," so as to give the broadest possible meaning to interrogatories and definitions containing those words.

16. As used herein, "and" and "or" shall be construed conjunctively and disjunctively so as to acquire the broadest meaning possible.

17. As used herein, "any" and "all" shall each be construed to mean "each and every," so as to acquire the broadest meaning possible.

18. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

19. As used herein, "related" or "relating" to any given subject means, without limitation, identifying, describing, discussing, concerning, assessing, stating, reflecting constituting, containing, embodying, tending to support or refute, or referring directly or indirectly to, in any way, the particular subject matter identified.

20. As used herein, "identify" as applied to a document shall mean to specify: (a) the type of the document (i.e., whether it is a letter, memorandum, e-mail, etc.); (b) the document's title and general subject matter; (c) the number of pages of the document; (d) the date the document was prepared; (e) the name of each and every author, addressee, distributor, and recipient of the document; (f) the date each distributor distributed the document and the date each recipient received the document; and (g) the name of each person that has or had possession, custody, or control of the document.

21. Any term not specifically defined herein shall be defined in accordance with normal usage as well as with the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of Delaware.

INSTRUCTIONS FOR REQUESTS FOR PRODUCTION

1. Apple's Requests for Production seek responsive documents and information sufficient to answer each of the Requests that are known or available You or in Your possession, custody, or control. If, after exercising due diligence to secure the documents or information requested, You cannot fully respond to a Request for Production, state that such is the case and answer to the fullest extent possible, stating what responsive documents or information are available, what documents or information cannot be provided, why the documents or information are unavailable, and what efforts were made to obtain the unavailable documents or information. If documents or information responsive to a Request in this subpoena are in Your control, but not in Your possession or custody, promptly identify the entity with possession or custody.

2. Regardless of whether a production is in electronic or paper format, documents that were maintained together before production should be produced in the same form, sequence, organization, or other order or layout as they were maintained, including any labels, file folders, file jackets, covers, or containers in which such documents are located or with which such documents are associated. If copies of documents are produced in lieu of the originals, such copies should be legible and bound or stapled in the same manner as the original.

3. These Requests for Production shall be deemed continuing. Documents located, and information learned or acquired, at any time after Your response is due must be promptly supplemented at the place specified in this subpoena.

4. A copy of the Protective Order entered in this Action for the protection of any requested proprietary, confidential, or commercially sensitive information is attached hereto.

REQUESTS FOR PRODUCTION

1. Documents sufficient to identify and describe the functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products and all components, modules, applications, hardware, software, and firmware contained therein, including, without limitation, user manuals, brochures, presentations, user guides, product literature, engineering specifications, circuit diagrams, architectural diagrams, bills of materials, technical manuals, product specifications, data sheets, laboratory notebooks, research papers, test data and results, analyses, invention disclosure forms, reports, service manuals, operator's manuals, implementation guides, white papers, product tutorials, and non-public documentation.

2. Documents sufficient to identify and describe the conception, design, research, development, testing, use, operation, maintenance, marketing, modifying, sale, offer for sale, and supply of the Relevant Products, including the persons and entities involved.

3. Documents, communications, and things comparing the Apple Watch to the Relevant Products.

4. Other versions of the Exhibits and documentation related to the Exhibits.

5. Documents sufficient to show the earliest dates that each of the Relevant Products were first conceived; reduced to practice; and made, sold, used (including by third parties such as end users), offered for sale, in public use, and otherwise available to the public in the United States, including but not limited to documents relating to any conference, seminar, exhibition, convention, or trade show at which such Product is or was discussed, referred to, advertised, displayed, demonstrated, or shown, such as, without limitation, product specifications, catalogs, announcements, advertisements, brochures, articles, pamphlets, price lists, invoices, purchase orders, sales records, or other promotional, marketing, or sales materials.

6. Publications related to the Relevant Products that were made available to the public.

7. Three samples of each Relevant Product.

8. Source Code sufficient to show the functionality of the Blood Oxygen and Heart Rate Features of the Relevant Products.

9. Documents sufficient to show the authorship and authenticity of all the documents produced in response to this subpoena.

DEPOSITION TOPICS

1. The functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products.

2. The earliest dates that each Relevant Product was reduced to practice, made, sold, offered for sale, in public use, or otherwise available to the public.

3. The subject matter contained within the documents produced in response to Requests For Production herein, including the authentication thereof.

4. The authorship and authenticity of the documents produced in response to the Requests For Production herein.

EXHIBIT 1

9560 Onyx® II

The Onyx®II, the most trusted name in fingertip pulse oximetry, is now integrated with Bluetooth Wireless Technology allowing patients to take vital signs anytime, anywhere.

Bluetooth®

- Bluetooth® 2.0 Wireless Technology
- Store & Forward Memory
- Extended Range up to 100m
- SmartPoint™ Technology
- Power Saver
- Patient Proof

NONIN PureSAT® | SpO_2

NONIN® Right. When you need it.™

Oximetry Unplugged™ – Revolutionizing Disease Management

With the increased need for remote disease management, the Onyx II, Model 9560 with Bluetooth® wireless technology provides a pulse oximetry monitoring solution that simplifies the exchange of secure information. The integration of interoperable, Bluetooth wireless technology in health monitoring devices will allow patients, along with their clinicians, to more easily monitor vital signs in environments never before possible. As a result, patients will be able to go about their daily activities and send their vital data wirelessly through communication devices such as cell phones, PDAs and PCs, etc.

The benefits of this revolutionary product also include dramatic cost savings and reducing the strain put on over-crowded healthcare facilities. By working to streamline the monitoring/data sharing process, breakthrough devices such as the Onyx II 9560 enable clinicians to remotely monitor patients with chronic diseases such as Chronic Obstructive Pulmonary Disease (COPD), Congestive Heart Failure (CHF) or Asthma.

Onyx® II 9560 – A Closer Look

Bluetooth® 2.0 Technology

Engineered with Bluetooth 2.0 Wireless Technology, the Onyx II 9560 provides a secure wireless connection for vital information exchange. Extremely versatile, it easily connects to communication devices (cell phones, PDAs, PCs, etc.). More importantly, the 9560 is designed to meet the requirements of the emerging Bluetooth Health Device Profile (HDP), IEEE 11073 and Continua standards.

Store & Forward Memory

Ensures ultimate versatility by allowing patients to take readings when a wireless connection is not possible. When the patient returns into range, The Onyx II 9560 automatically transmits the time-stamped data. The Onyx II 9560's memory storage provides a minimum of 20 single point measurements.

SmartPoint™ Technology

SmartPoint Technology provides a fast and accurate snapshot of the patient's SpO_2 and pulse rate and eliminates the guesswork of determining which oximetry values to use for analysis. The SmartPoint algorithm automatically determines when a high quality measurement is ready to be wirelessly transmitted and each measurement includes an indicator of quality.

Clinically Proven Oximetry

Since 1995, Over One Million Onyx Devices Sold

The Nonin Onyx is the most widely used and trusted fingertip pulse oximeter by clinicians and patients worldwide. The Onyx is a proven performer with the widest range of patients from pediatric to adult, light to dark skin tones and good to low perfusion. The accuracy of Onyx fingertip oximeters is a result of Nonin Medical's superior PureSAT® signal processing technology that removes noise, artifact and/or interference that may affect readings — providing consistently accurate oximetry readings you can depend on.

Onyx®, The World's First Fingertip Pulse Oximeter

Revolutionary Onyx II, Model 9560

Onyx® II, Model 9560 - The World's First Bluetooth® Wireless Fingertip Pulse Oximeter

The Onyx II, Model 9560 with Bluetooth wireless technology is designed with our proven PureSAT® oximetry technology and delivers the trusted, precision accuracy of the entire Onyx line. And now with the advantage of wireless monitoring capabilities — the built to last and easy-to-use Onyx II 9560 provides unparalleled versatility for patient and clinician. Plus, with the addition of innovative new features such as Extended Range and Power Saver — it's ideal for home patient use.

Extended Range

The Onyx II 9560 provides an extended range of up to 100 meters (Class I) for added mobility and independence.

Patient Proof

Unmatched durability for the home care environment, we've made the Onyx II 9560 rugged to take a beating day after day. The most widely used fingertip oximeter comes with no wires or cables to hassle with, an automatic turn on/turn off, and is as convenient and easy-to-use as possible.

Power Saver™

Unlike traditional Bluetooth devices, the Onyx II 9560 has a new power saving feature that automatically adjusts transmitted power based on distance from the main unit. This unique feature allows for approximately 600 spot checks on 2 AAA batteries.

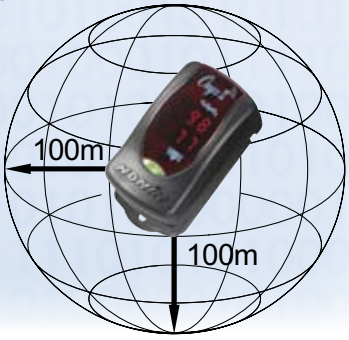
Why Bluetooth®

Bluetooth is a proven and widely accepted technology that provides freedom from wired connections. An automatic wireless connection provides fast, reliable and secure transmissions of data even when the devices are not in line-of-sight. Bluetooth uses a license-free, globally available frequency range in the Industrial Scientific Medical (ISM) band — to ensure communication compatibility worldwide.

Nonin products continue to revolutionize the way you look at pulse oximetry. With the integration of Bluetooth Wireless 2.0 Technology into the Onyx II 9560 Fingertip Pulse Oximeters, Nonin is the first to eliminate the wire between the patient and the display.

The choice of Bluetooth Wireless Technology also offers other advantages:

- ✓ Internationally accepted communication standard
- ✓ Ideal for short and long-range use up to a 100 meter radius
- ✓ Low power for long battery life
- ✓ Technology allows for compact design
- ✓ Reliable connections
- ✓ Data encryption feature to safeguard patient data



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Toll Free: 800.356.8874

Your Partner of Choice. With more than 20 years of experience and dedication to the design and support of noninvasive monitoring devices, NONIN has helped many medical professionals meet clinical and economic objectives. Trusted by clinicians worldwide, countless tests are performed every day using NONIN pulse oximeters in more than 125 countries. More than 90 OEM partners around the world also rely on NONIN's digital technology to successfully integrate superior pulse oximetry and capnography into their products. NONIN's dedication to technological leadership, precision manufacturing and uncompromised customer support ensures quality products and service you expect.

www.nonin.com

Specifications

Oxygen Saturation Display Range	0 – 100% SpO_2
Pulse Rate Display Range	18 to 321 beats per minute (BPM)
Oxygen Saturation Declared Accuracy Range (A_{rms}*)	70 – 100% SpO_2 ±2 digits
Low Perfusion Oxygen Saturation Declared Accuracy Range (A_{rms}*)	70 – 100% SpO_2 ±2 digits
Pulse Rate Declared Accuracy Range (A_{rms}*)	20 – 250 BPM ±3 digits
Low Perfusion Pulse Rate Declared Accuracy Range (A_{rms}*)	40 – 240 ±3 digits
Measurement Wavelengths and Output Power**	
Red:	660 nanometers @ 0.8 mw maximum average
Infrared:	910 nanometers @ 1.2 mw maximum average
Temperature	
Operating:	+41° to +104°F / 5° to +40°C
Storage/Transportation:	-40° to +158°F / -40° to +70°C
Humidity	
Operating:	10 – 95% noncondensing
Storage/Transportation:	10 – 95% noncondensing
Altitude	
Operating:	Up to 40,000 feet / 12,192 meters
Hyperbaric Pressure:	Up to 4 atmospheres
Battery Life	
Operating:	Approximately 600 spot checks
Storage:	1 year, minimum

Antenna	
Type:	L-shaped PWB whip-type antenna
Transmitter	
Bluetooth Compliance:	Version 2.0
Operating Frequency:	2.4 – 2.4835 GHz
Output Power:	<20 dBm
Operating Range:	100-meter radius indoors***
Network Topology:	Star
Operation:	Bluetooth Slave
Antenna Type:	Internal
Modulation Type:	Gaussian Frequency Shift Keying (GFSK)
Frequency Hopping Spread Spectrum	
Band Width:	1 MHz

Classifications per IEC 60601-1 / CSA 601.1 / UL 60601-1

Degree of Protection:	Type BF-Applied Part
Enclosure Degree of Ingress Protection:	IP32
Mode of Operation:	Continuous

This product complies with ISO 10993-1.

*± 1 Arms represents approximately 68% of measurements.
**This information is especially useful for clinicians performing photodynamic therapy.
***Line of sight when connected to a Class I device.

Specifications are subject to change without notice.

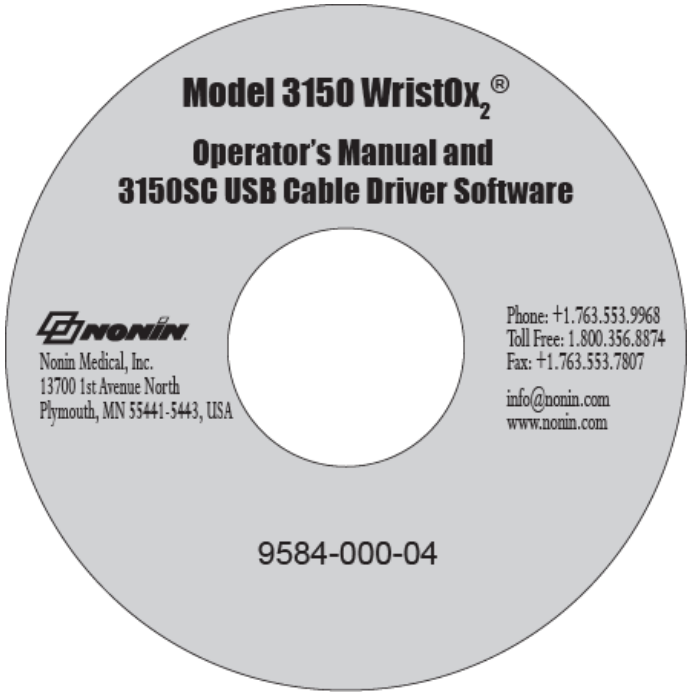
UL 60601-1 30EM

NONIN PureSAT® | SpO_2

6459-001-01

EXHIBIT 2

Rev.	CR/CO	Date	Orig.
A	8781	12/09/13	PDL
B	9001	05/06/14	MLJ
C	9213	09/11/14	MLJ
D	10199	7/13/16	MLJ



NOTES:

1. **Compact Disk**
   Material: Standard 12cm CD, replication or duplication
   Text and graphics: Black 1/c screen
   CD Graphics per Nonin electronic file 9584-000-04.eps
2. **Packaging**
   Material: White paper sleeve with clear window. CD text and graphics must be visible through clear window.
3. See sheet 2 for Master CD Directory.
4. Sheet 3 of 3 is the CD.

Prepared By	Date	
MLJ	06/13/16	
Checked By	Date	
BAK	7/14/16	

NONIN® MEDICAL, INC. MINNEAPOLIS, MN

Title:	Part Number	Rev	Sheet
OPERATORS MANUAL (CD), 3150	9584-000	D	1 of 2

MODEL 3150 OPERATOR'S MANUAL

MASTER CD DIRECTORY

CD Directory:

Volume in drive E is 3150 WristOx2
Volume Serial Number is D42B-E542

```
11/13/2015  02:33 PM           309,425  8266-000-03_SensorAccuracy.pdf
06/13/2016  03:25 PM    <DIR>           Operators Manuals
10/01/2015  03:07 PM    <DIR>           USB Driver
               1 File(s)        309,425 bytes
```

Directory of Operators Manuals

```
06/13/2016  03:25 PM    <DIR>          .
06/13/2016  03:25 PM    <DIR>          ..
06/13/2016  03:15 PM         5,816,529  9584-001-04_3150_OperatorsManual_ENG.pdf
06/06/2016  01:26 PM         5,934,574  9584-002-04_3150_OperatorsManual_FRE.pdf
06/06/2016  03:53 PM         5,933,868  9584-003-04_3150_OperatorsManual_GER.pdf
06/06/2016  03:37 PM         6,541,624  9584-004-04_3150_OperatorsManual_ITA.pdf
06/13/2016  01:43 PM         5,835,841  9584-005-04_3150_OperatorsManual_SPA.pdf
06/07/2016  08:11 AM         5,905,837  9584-006-04_3150_OperatorsManual_POR.pdf
06/07/2016  09:29 AM         5,885,692  9584-007-04_3150_OperatorsManual_DUT.pdf
06/07/2016  10:27 AM         6,264,182  9584-008-04_3150_OperatorsManual_GRK.pdf
06/07/2016  11:50 AM         5,743,415  9584-009-04_3150_OperatorsManual_DAN.pdf
06/07/2016  01:43 PM         5,716,940  9584-010-04_3150_OperatorsManual_SWE.pdf
06/07/2016  02:07 PM         5,750,198  9584-011-04_3150_OperatorsManual_FIN.pdf
06/07/2016  03:18 PM         6,158,175  9584-012-04_3150_OperatorsManual_POL.pdf
06/13/2016  01:51 PM         5,772,387  9584-016-04_3150_OperatorsManual_NOR.pdf
              13 File(s)     77,259,262 bytes
```

Directory of USB Driver

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10/01/2015  03:07 PM    <DIR>          .
06/13/2016  03:25 PM    <DIR>          ..
12/12/2013  09:02 AM             2,068 NoninUSBDriver-CDC.inf
12/12/2013  09:02 AM             8,661 nonin.cat
               2 File(s)         10,729 bytes
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Total Files Listed:

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              16 File(s)     77,579,416 bytes
               6 Dir(s)               0 bytes free
```

Title:	Part Number	Rev	Sheet
OPERATORS MANUAL (CD), 3150	9584-000	D	2 of 2

Operator's Manual

Model 3150
WristOx$_2$® Pulse Oximeter

Wrist-Worn Pulse Oximeter with Bluetooth® Wireless Technology

CE 0123

English

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Consult Instructions for Use.

Nonin® reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

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CE 0123

EC REP

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References to “Nonin” in this manual imply Nonin Medical, Inc.

9584-001-04

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Indications for Use

The Nonin WristOx$_2$®, Model 3150 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (%SpO$_2$) and pulse rate. It is intended for spot-checking and/or data collection and recording of adult and pediatric patients, during both no motion and motion conditions, and for patients who are well or poorly perfused. The intended use environments are hospitals, medical facilities, ambulatory, subacute, and sleep study environments, and mobile units.

Warnings

Do not use this device in a Magnetic Resonance (MR) environment or in the presence of flammable anesthetics or gases.
This device is not defibrillation proof per IEC 60601-1.
This device is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
Check the pulse oximeter sensor application site every 4 hours to determine the positioning of the sensor and the circulation and skin sensitivity of the patient. Patient sensitivity varies depending on medical status or skin condition.
Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
Carefully route patient cables and connections to reduce the possibility of patient entanglement, strangulation, or injury to the patient.
To avoid patient injury, use only Nonin-branded PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Nonin pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.
To prevent improper performance and/or patient injury, verify compatibility of the monitor, sensor(s), and accessories before use.
No modifications to this device are allowed as it may affect device performance.
The USB cable must be unplugged from the device before replacing batteries.
Before changing the batteries, make sure the device is off and the sensor is not applied to a digit.
This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.
The use of accessories, sensors, and cables other than those listed in this manual may result in increased electromagnetic emission and/or decreased immunity of this device.
Do not use the device when alarms are required.
Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
This equipment complies with International IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.

Cautions

If this device fails to respond as described, refer to “Troubleshooting” or discontinue use until the situation has been corrected. Contact Nonin Technical Service.
This device has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the device may still interpret motion as good pulse quality.
Do not place liquids on top of this device.
When setting the clock in Programmed Mode using nVISION software, verify all set times and dates are valid.
Do not place the WristOx$_2$, Model 3150, in liquid or clean it with agents containing ammonium chloride or isopropyl alcohol. Refer to the “Care and Maintenance” section of this operator’s manual.
Use a detergent that is safe for skin and washable surfaces. Most detergents can be high sudsing, so use sparingly. Wipe with a damp, detergent free cloth to remove residue.
After cleaning the single-patient use wristband, it should only be applied to the same patient; do not apply it to a different patient.
Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device. If you are unsure how to reach your distributor, please call Nonin for your distributor’s contact information.
This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following: - excessive ambient light - excessive motion - electrosurgical interference - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.) - moisture in the sensor - improperly applied sensor - incorrect sensor type - poor pulse quality - venous pulsations - anemia or low hemoglobin concentrations - cardiogreen and other intravascular dyes - carboxyhemoglobin - methemoglobin - dysfunctional hemoglobin - artificial nails or fingernail polish - residue (e.g., dried blood, dirt, grease, oil) in the light path
When using the monitor in the home, avoid exposing the monitor to lint and dust.
When using the monitor around small children and pets, avoid leaving the monitor unattended. Cables pose a risk of injury, including strangulation.
Do not perform any testing or maintenance on this device while it is being used to monitor a patient.
This device is a precision electronic instrument and must be repaired by Nonin Technical Service. Field repair of this device is not possible. Except to replace batteries, do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
Verify all visible indicators appear during the start-up (initialization) sequence. If any indicator does not appear, do not use the device. Contact Nonin Technical Service for assistance.
Portable and mobile RF communications equipment can affect medical electrical equipment.
Batteries may leak or explode if used or disposed of improperly. Remove batteries if the device will be stored for more than 30 days. Do not use different types of batteries at the same time. Do not mix fully charged and partially charged batteries at the same time. These actions may cause the batteries to leak.
To avoid the risk of confusing or misinterpreting patient data when transmitting data via Bluetooth, verify the device is paired with the correct display unit.
The pulse oximeter may not work when circulation is reduced. Warm or rub the finger or reposition the sensor.

Cautions (Continued)

A functional tester cannot be used to assess the accuracy of the oximeter or sensor.
Do not fasten the device too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.
If the WristOx$_2$, Model 3150 is being used with wireless communication, use the device within its designated range of approximately 100 meters (spherical radius). Moving outside this range may cause missing or lost data.
Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.

Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility

- Nonin Medical, Inc., of 13700 1st Avenue North, Plymouth, Minnesota, 55441, declares under its sole responsibility that Model 3150, WristOx$_2$ Pulse Oximeter, to which this declaration relates, complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Ministry of Health (Canada), Safety Code 6: standards include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg.

NCC

警語低功率電波輻射性電機管理辦法第十二條經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。第十四條低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前項合法通信，指依電信規定作業之無線電信。低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾

在 5.25-5.35 秭赫頻帶?操作之無線資訊傳輸設備，限於室?使用。

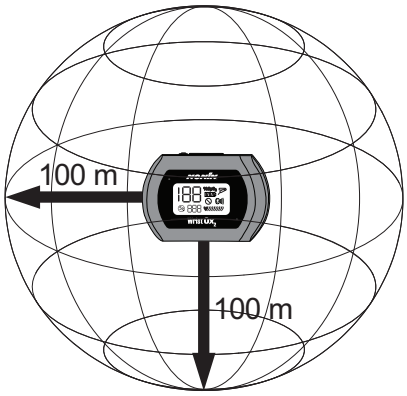
Federal Communications Commission (FCC) Notice

This device has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the device off and on. The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the device and the receiver.

- Connect the device to an outlet on a circuit different from the outlet where the receiver is connected
- Consult the dealer or an experienced radio/TV technician for assistance.
- RF Exposure: For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain no metallic components. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.
- The WristOx$_2$, Model 3150, is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the United States FCC. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This device has been shown to be compliant for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-2005.
- The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the device.

Nonin's use of Bluetooth wireless technology allows SpO_2, pulse rate, and plethysmographic data to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device. Nonin's system removes the connection from the sensor cable to the display device, giving patients increased ability to move freely—without being hindered by cables. Nonin's patient module uses a Bluetooth radio with a range of about 100 meters (328 feet) (spherical radius).



Point-to-Point Communications

The WristOx$_2$, Model 3150, features point-to-point communications, allowing one master device (the display device) to be paired to one slave device (the patient module). Once connected, neither device is detectable by any other Bluetooth-enabled device, which reduces the risk of interference and preserves data integrity.

> ⚠ **CAUTION:** If the WristOx$_2$, Model 3150 is being used with wireless communication, use the device within its designated range of approximately 100 meters (spherical radius). Moving outside this range may cause missing or lost data.

Guide to Symbols

This chapter describes the symbols that are found in this manual and on the WristOx$_2$, Model 3150. Detailed information about display symbols can be found in “Displays, Controls, and Indicators.”

Table 1: Labeling Symbols

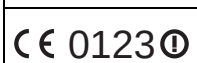
Symbol	Description
	Caution!
	Consult Instructions for Use.
	Follow Instructions for Use.
	Authorized Representative in the European Community.
	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
	Type BF-Applied Part (patient isolation from electrical shock)
	No alarms
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Continua Certified™ signifies that this product has been tested and proven to be interoperable with other products that carry the Continua Certified symbol.
	Bluetooth® figure mark
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with: • ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008) • ISO 80601-2-61:2011
IP33	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.

Table 1: Labeling Symbols (Continued)

Symbol	Description
	Manufacturer
	Serial Number
	Catalogue Number
	Quantity
	Date of Manufacture
	Country of Manufacture
	Storage/shipping Temperature Range
	RoHS Compliant (China)
	Medical prescription required

Displays, Controls, and Indicators

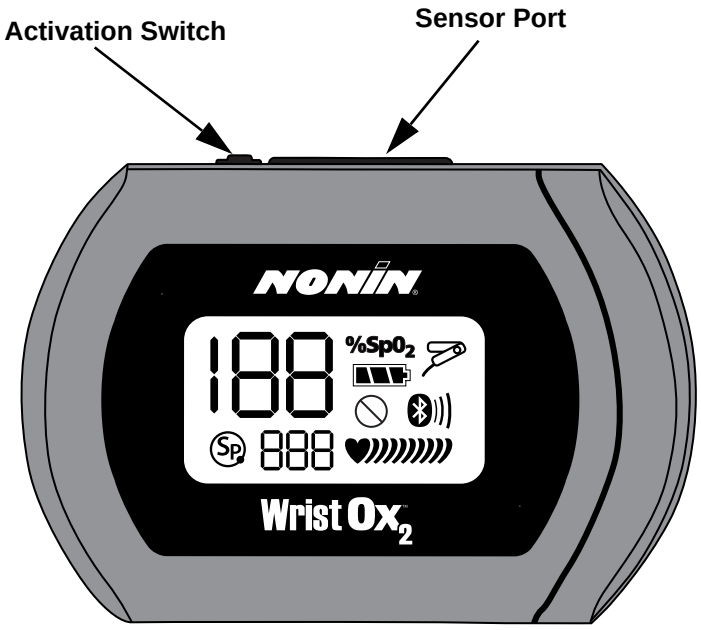


Figure 1: Front Display (Startup Screen)

%SpO$_2$ Display

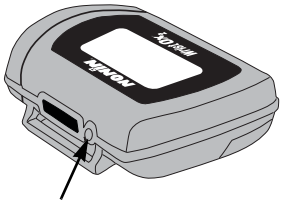
This 3-digit display, located in the upper left corner of the LCD, shows percent blood oxygen saturation (%SpO$_2$). The range is from 0 to 100 %.

This display also shows the month, year, and hour (24-hour clock format) during startup.

Pulse Rate Display

This 3-digit display, located below the %SpO$_2$ display, shows the pulse rate in beats per minute (BPM). The range is from 18 to 321 BPM.

This display also shows the day and minute during startup.



Activation Switch

This switch is located next to the sensor port.

Pressing this switch activates the Bluetooth radio for 3 minutes.

It can also be used to turn the device on when it is in Standby mode. See “Activation Switch” section for more information.

Sensor Fault Indicator

This indicator displays if the device determines a sensor fault exists (e.g., sensor disconnect, misalignment, or incompatibility with the device). It also displays when the finger is removed from the sensor.

Pulse Strength Indicator

A pulse strength indicator displays when the device is recording data. The number bars on the display depends on the pulse strength as determined by the oximeter.

Full and Partial Display Mode

Full and Partial Display Mode – This heart-shaped indicator is followed by up to nine curved bars and displays next to the pulse rate.

Memory Volume Display Mode

Memory Volume (MVI) Display Mode – This indicator consists of up to nine curved bars and displays next to the minutes of stored data. For more information, see “Memory Volume (MVI) Display Mode” on page 14.

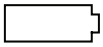
Poor Pulse Signal Indicator

This indicator displays when the pulse signal is inadequate or the device does not sense a pulse. It may also display if there is excessive motion at the sensor site.

Full 

Half 

Low 

Critical 

Battery Indicator

This indicator shows remaining battery life as either full, half, low, and critical (as shown at left).

Replace the batteries when device reaches low state.

When the battery reaches critical state:

- All indicators clear from the display except for the blinking critical battery indicator.
- The current session closes.
- The Bluetooth radio shuts down.
- The clock settings are lost.
- The device reverts to Spot Check mode.

Bluetooth indicator

Bluetooth Indicator

This indicator displays when the Bluetooth radio is on. It appears as either the Bluetooth logo or the Bluetooth logo with animated bars.

This indicator displays for the first 2 minutes the device is on. If a master device does not connect to the device in those 2 minutes, the Bluetooth radio shuts down and the icon no longer displays.

Bluetooth indicator with animated bars

When the device is connected to a master device, the indicator displays with animated bars.

If the Bluetooth radio is on when the device enters Standby mode or connects to the USB interface cable, the Bluetooth indicator appears on the LCD while the Bluetooth radio shuts down. It will be the only indicator on the LCD and will display for up to 10 seconds.

SmartPoint Indicator

This indicator displays during the startup sequence.

Introduction

The Bluetooth-enabled WristOx$_2$, Model 3150, is a small, wrist-worn device that displays, measures, and stores patient SpO_2 and pulse rate data. The device includes a Bluetooth radio with a range (spherical radius) of approximately 100 meters (328 feet).

The device ships ready to use in Spot Check turn on mode. In Spot Check turn on mode, inserting a finger in the sensor automatically turns the device on. Approximately 10 seconds after the finger is removed, the device enters Standby mode.

Advanced memory and programming features are available with Nonin's nVISION® software (version 6.3 or greater). See the "nVISION Software" section to learn more about using the device with nVISION.

NOTE: If using the WristOx$_2$, Model 3150 with 3rd party software, please disregard nVISION information.

Unpacking the WristOx$_2$, Model 3150

The WristOx$_2$, Model 3150, standard or starter kit includes the items listed below. Once the shipping carton is unpacked, verify these items were received. Contact the carrier immediately if the shipping carton is damaged.

Standard Kit

- Model 3150, WristOx$_2$ Pulse Oximeter
- Model 8000SM-WO2, reusable soft sensor
- 1 wristband
- 2 AAA (1.5 volt) alkaline batteries
- Operator's manual (CD)
- USB driver software (on operator's manual CD) – required to use the PC USB interface cable

Starter Kit

A starter kit is required to configure the device and download data to a PC. The starter kit consists of the standard kit, plus:

- 3 wristbands
- nVISION SpO_2 data management software (CD)
- Model 3150SC, PC USB interface cable

Batteries

The device uses 2 AAA batteries.

With new alkaline batteries, battery life is approximately 53 hours (minimum) when not connected to a Bluetooth device. When connected to a Bluetooth device, battery life will vary depending on class of operation. See "Specifications" for detailed battery life information.

The battery indicator shows one of four states: full, half, low, and critical. Replace the batteries when device reaches low state. A low battery has a minimum of 10 minutes before it reaches critical state. Actual battery life depends on Bluetooth radio use. In critical battery mode:

- The battery indicator blinks.
- The device no longer monitors or records patient data.
- The clock settings are lost.
- The device reverts to Spot Check mode.

When batteries are removed in low battery mode, the device maintains the time and date for up to 30 seconds. After battery replacement, check the device's screen during startup to ensure date and time are set. Use nVISION software to synchronize the clock and change the operation mode (see "Accessing nVISION Settings" on page 29).

Remove the batteries and disconnect the sensor if the device is to be stored for more than 1 month. In storage, battery life is approximately 9 months.

NOTES:

- This device contains non-volatile memory. Removing or replacing batteries does not affect the data stored in memory. Stored data remains in memory until overwritten by newer data or cleared from memory with nVISION software (version 6.3 or greater).
- If batteries are replaced while recording data, the session will terminate and some data from the session may not be saved. The terminated session will be time stamped with the current date/time the next time the device turns on.
- To avoid potential battery cell damage for all battery types, remove batteries from the device when the critical battery indicator displays. Leaving rechargeable batteries in the device during critical battery will decrease battery life.
- If clock settings are lost, the date and time restarts at 01:01:10:00:00.

Bluetooth Technology

Bluetooth technology allows wireless connections between electronic communications and computing devices. The technology is based on a radio link that offers fast and reliable data transmissions. Bluetooth uses a license-free, globally available frequency range in the ISM band—intended to ensure communication compatibility worldwide.

Nonin's use of Bluetooth wireless technology allows SpO_2 and pulse rate data to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device. Nonin's wireless system removes the cable connection from the device, giving patients increased ability to move freely.

To make efficient use of battery life, Nonin's WristOx$_2$, Model 3150, uses an automatically switchable Class 1/Class 2 Bluetooth radio with a maximum range (spherical radius) of about 100 meters (328 feet). Obstacles and other conditions may affect range, and class of operation and connection mode will impact battery life. See "Specifications" for detailed battery life information.

Operation Modes

The WristOx$_2$, Model 3150, has three states: Cable, Standby, and On.

Cable

The device is in Cable mode when it is connected to a PC using the USB interface cable. While in Cable mode, the device does not collect or save data and the Bluetooth radio is off.

NOTE: To save battery life, the Model 3150 will automatically shut off after 60 minutes when it is connected to a PC using the USB interface cable.

Standby

When the device is in Standby mode, the screen is blank and the device appears to be off. In Standby, it is ready for a signal that will turn the device on (e.g., pressing activation switch, inserting finger in sensor [Spot Check mode], connecting sensor [Sensor Activation mode], or programmed start time [Programmed mode]). While in Standby mode, the device does not collect or save data and the Bluetooth radio is off.

On

When the device is on, it can collect and save data. The device features three turn on modes:

- Spot Check mode
- Sensor Activation mode
- Programmed mode

The device is delivered in Spot Check mode. nVISION software (version 6.3 or greater) is needed to access the device settings and change Spot Check mode to Sensor Activation or Programmed mode (see “nVISION Software”). nVISION software (version 6.4 or greater) is needed to access memory volume (MVI) display mode.

The device recalls the active settings when the device is shut off and turned on again.

Spot Check Mode

Spot Check mode is the default turn on operation mode.

The device automatically turns on when a finger is inserted into the sensor. It enters Standby mode 10 seconds after the finger is removed. If the sensor is disconnected, the device enters Standby mode immediately.

In this mode, the sensor can be left connected to the device.

NOTE: If the device determines that a sensor fault exists (a sensor failure, misalignment, or incompatibility with the device) or if a pulse oximeter sensor signal cannot be detected, the device enters Standby mode after 3 minutes.

Sensor Activation Mode

Sensor Activation mode may be selected through nVISION software. In this mode, the device turns on when the activation switch is pressed or when the sensor is disconnected and reconnected. This mode is useful when using a sensor that is not easily removed from the sensor site (e.g., disposable or wrap sensor).

NOTE: The sensor does not need to be applied to a finger to turn the device on.

If the sensor is not used for at least 10 minutes or if an inadequate pulse signal is detected, the device automatically enters Standby mode. To turn the device on again, press the activation switch or disconnect and reconnect the sensor.

This mode allows for Full or Partial display (see figure 2 for display comparison). When using Partial display, the SpO_2 and pulse rate readings do not display. The user will only see the battery indicator and the animated pulse strength indicator.

Full Display **Partial Display**

Figure 2: Comparison of Full and Partial Display

Programmed Mode

Programmed mode may be selected and setup through nVISION software. With the software, the user can program the device to start and stop for up to three sessions. Once programmed, the next start time displays on the LCD every 30 seconds in HH:MM format.

CAUTION: When setting the clock in Programmed Mode using nVISION software, verify all set times and dates are valid.

A sensor must be connected for Programmed mode to function.

If the programmed device is in Standby mode and the activation switch is pressed, the user activates the Bluetooth radio and the device for 3 minutes. During this time, the user is able to take and store measurements. After 3 minutes, the device returns to Standby mode.

This mode allows for Full or Partial display (see figure 2 above for display comparison). When using Partial display, the SpO_2 and pulse rate readings do not display. The user will only see the battery indicator and the animated pulse strength indicator.

NOTE: A programmed device reverts to Spot Check mode if the clock is not set or if the clock settings are lost when replacing the batteries.

Memory Volume (MVI) Display Mode

NOTE: When the device is in Memory Volume display mode, the %SpO_2 and pulse rate readings do not display on the screen.

MVI display mode is selected using nVISION software (version 6.4 or greater) or it can be enabled using an OEM command (refer to the Model 3150 OEM Specification and Technical Information for details). MVI display mode functions with all operating modes (spot check, sensor activation, and programmed).

Memory Volume display mode is used to quickly see how many hours and minutes of valid data are stored in the device's memory.

In Memory Volume display mode, the display screen (figure 3) only shows:

- The volume of data (in hours and minutes) stored in memory
  - hours: display range of 0 – 199
  - minutes: display range of 0 – 59
- The battery indicator
- The pulse strength indicator

When the animated pulse strength indicator displays, the device is recording data. The number next to the indicator are the minutes of stored data, not the pulse rate.

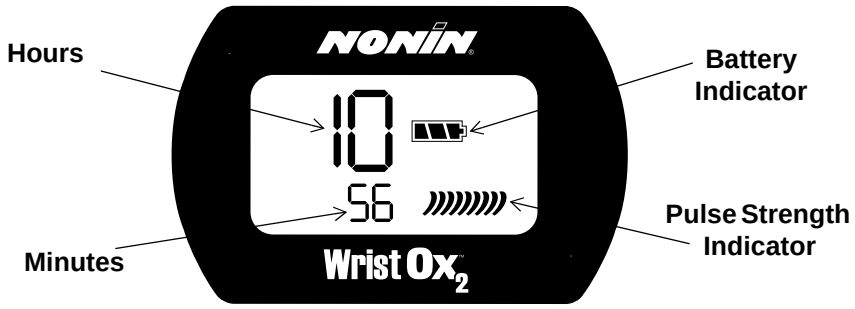


Figure 3: Memory Volume Display Mode

The example in figure 3 shows a device with 10 hours and 56 minutes of stored data.

Using the WristOx$_2$, Model 3150

WARNING: Do not use the device when alarms are required.

WARNING: The USB cable must be unplugged from the device before replacing batteries.

Installing Batteries

WARNING: Before changing the batteries, make sure the device is off and the sensor is not applied to a digit.

1. Open the battery compartment by sliding the battery door off the back of the device (figure 4).

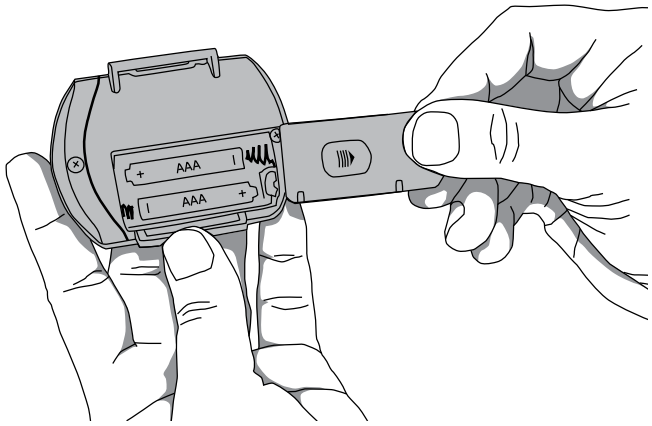


Figure 4: Remove Battery Door

2. Insert 2 new AAA batteries (figure 5). Battery orientation is shown inside the battery compartment.

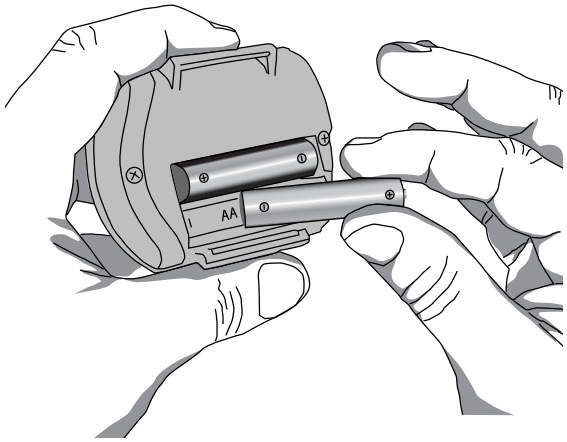


Figure 5: Insert Batteries

3. Replace battery door by sliding it back into place.

4. Inserting batteries does not turn the device on. In Spot Check mode, the device turns on when a finger is inserted in the sensor.

NOTE: When batteries are removed in low battery mode, the device maintains the time and date for up to 30 seconds. After battery replacement, check the device's screen during startup to ensure date and time are set. If the battery level is at or below the critical level, clock settings are lost and the device reverts to Spot Check mode. Use nVISION software to synchronize the clock and change the operation mode (see "Accessing nVISION Settings" on page 29).

Attaching the Wristband

The WristOx$_2$, Model 3150, is designed to be applied to the patient's wrist using a wristband.

This section contains instructions for attaching the wristband to the device. See the "Patient Application" section for instructions on how to apply the device to the patient.

Wristband Description

The adjustable wristband has a long segment, a short segment, and a plastic ring (figure 6). The wristband uses hook and loop fasteners to secure the wristband to the device and to the patient.

The long segment has two fasteners to accommodate a wide range of wrist sizes.

Figures 7 and 8 demonstrate how to attach the wristband to the device. Figure 9 shows front and back views of the attached wristband.

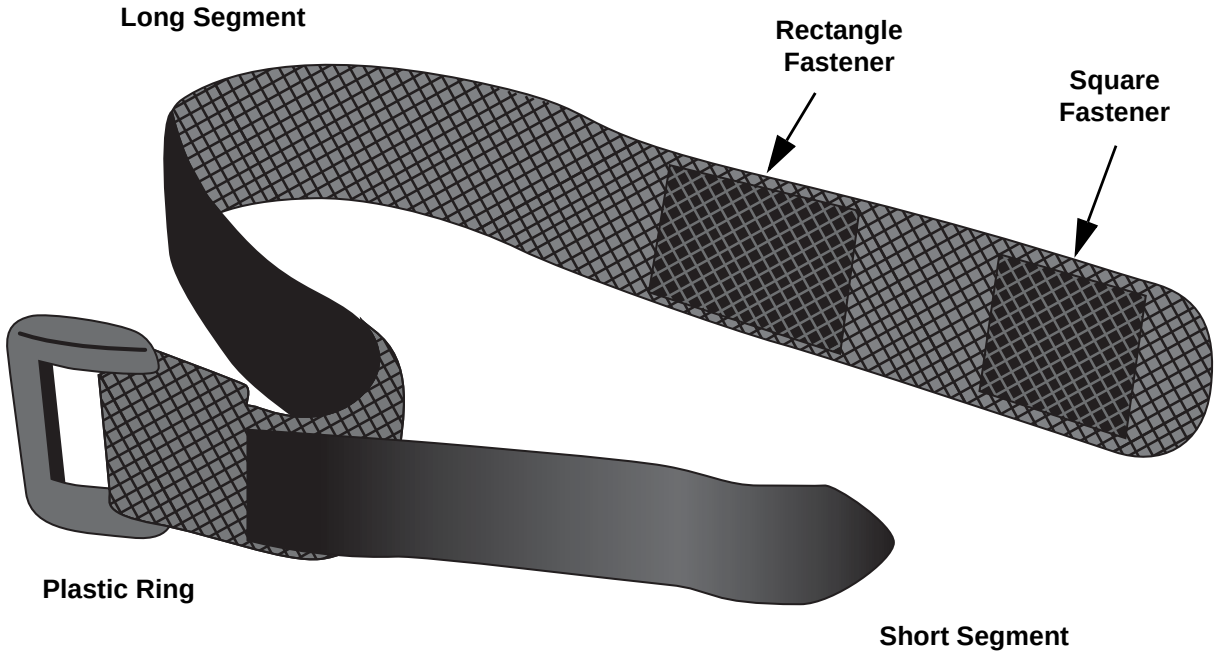


Figure 6: Wristband

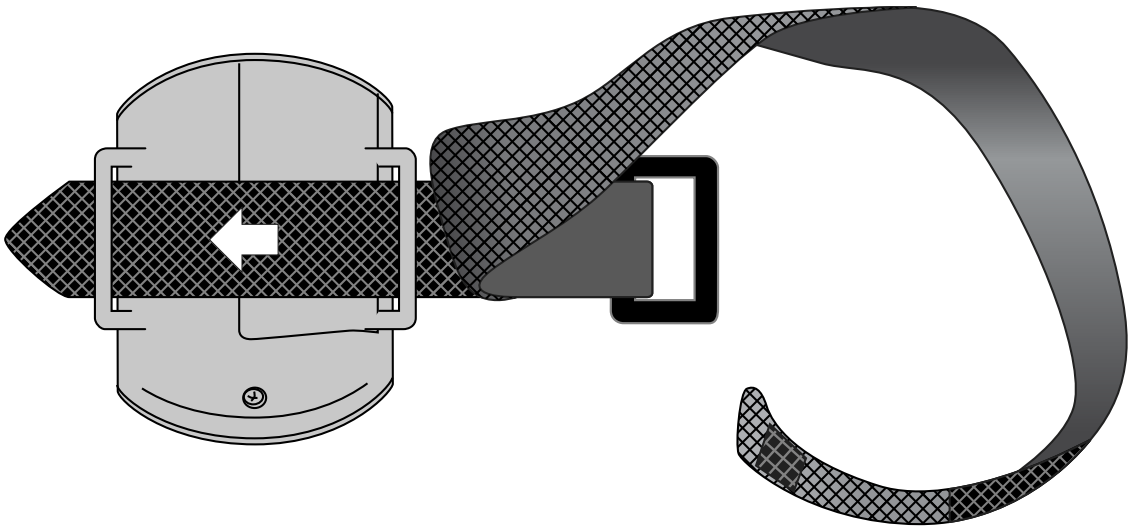


Figure 7: Thread Short Segment

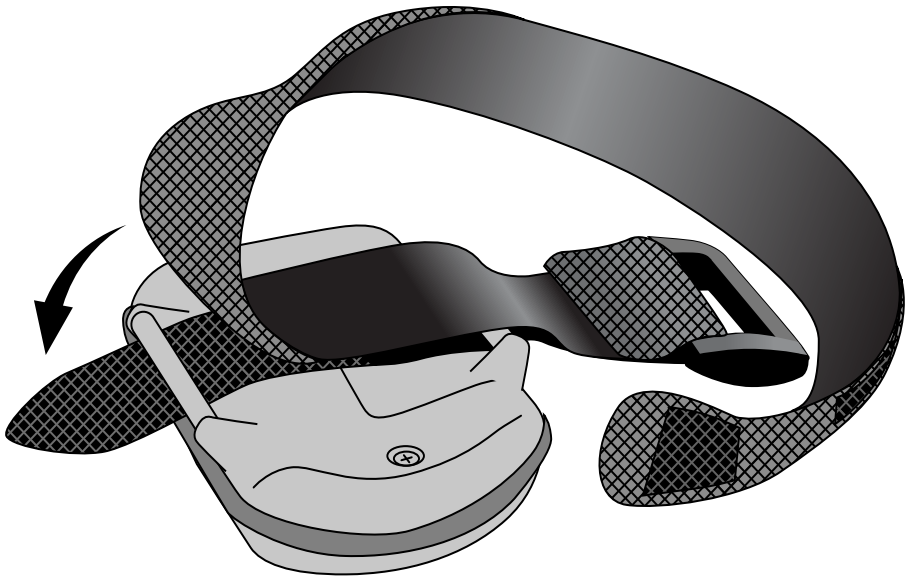


Figure 8: Secure Long Segment

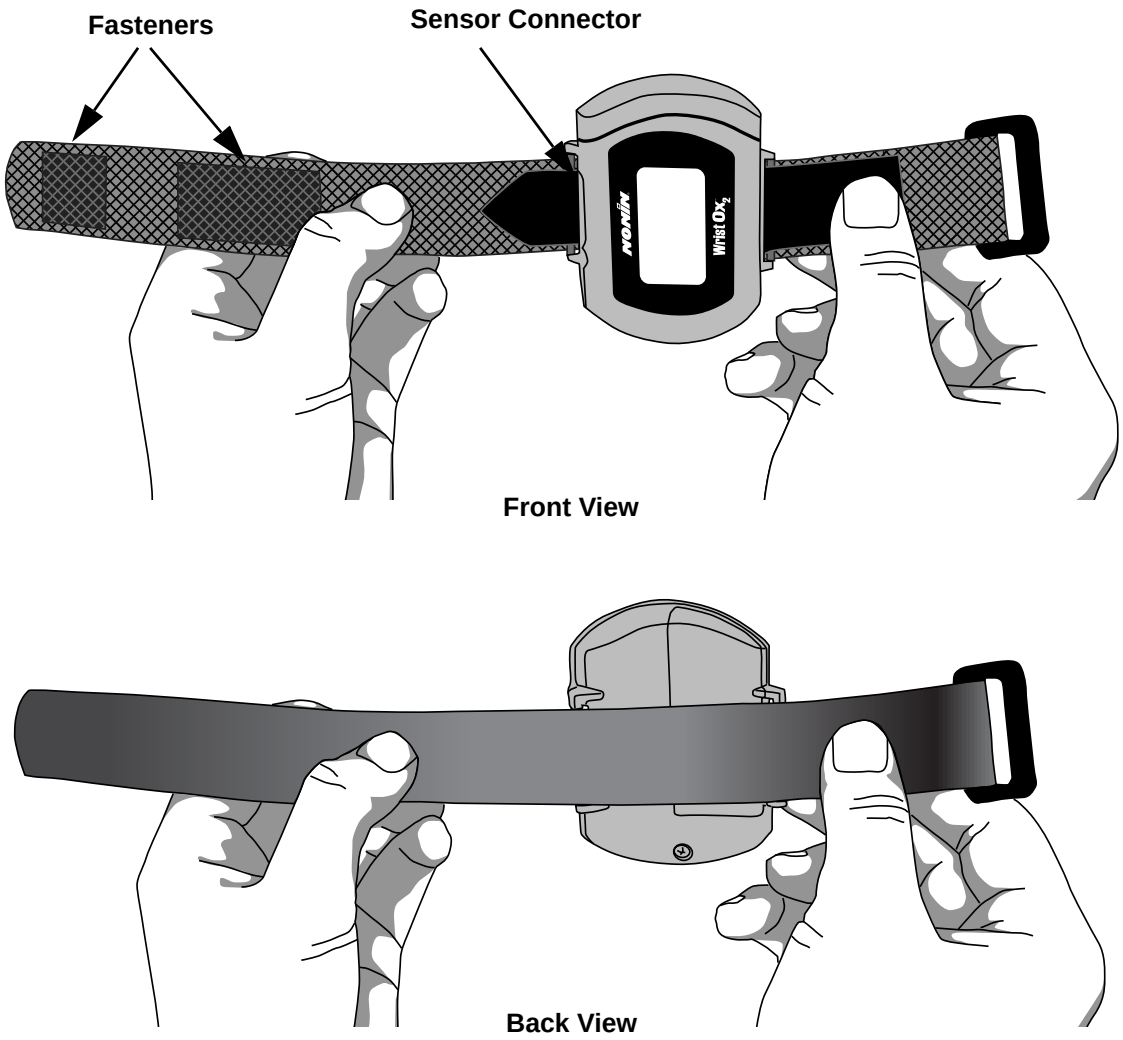


Figure 9: Device with Wristband Attached (Front and Back Views)

Attaching the Sensor

The sensor can be connected to the device before or after applying the device to the patient.

The following steps apply to these Nonin sensors:

- 8000SS-WO2, 8000SM-WO2, 8000SL-WO2
- 8000AA-WO2
- 8000J-WO2

NOTE: Refer to the sensor Instructions for Use for appropriate sensor sizing.

If using another Nonin-branded sensor, use sensor adapter cable 3150I (see “Parts and Accessories”).

WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.

1. Insert the sensor connector into the sensor port at the top of the device (figure 10). The Nonin logo on the sensor connector should face the front of the device.
2. Push the connector until it clicks into place.
3. The device is ready to use.

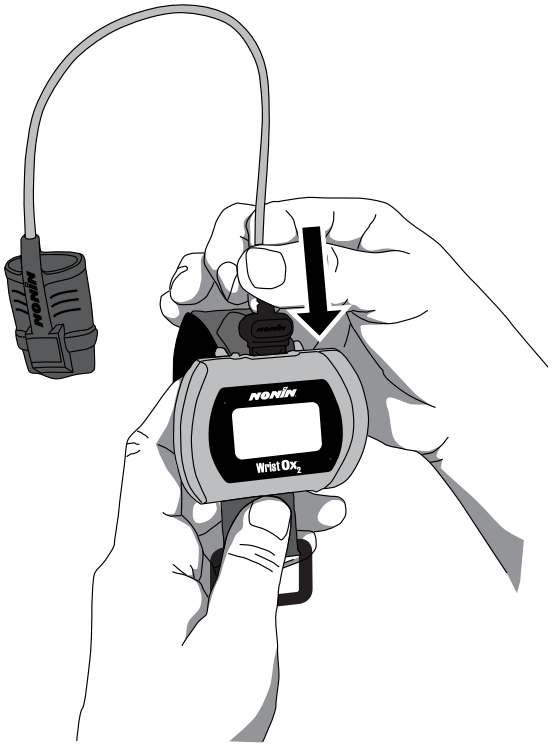


Figure 10: Attach Sensor

Patient Application

The WristOx$_{2,}$ Model 3150, is usually worn on the back of a patient's wrist.

NOTE: The wristband can be used to secure the device to an alternate location (e.g., the upper arm or a bed rail).

NOTE: Ensure the wristband fits comfortably on the patient's arm. Do not over-tighten the wrist band.

1. Verify the wristband has been attached properly to the device (figure 9). If the wristband has not been attached to the device, see "Attaching the Wristband."
2. Place the device on the patient's wrist.
3. Thread the rounded end of the wristband through the plastic ring. Pull the strap through the plastic ring until the device fits comfortably on the wrist (figure 11).

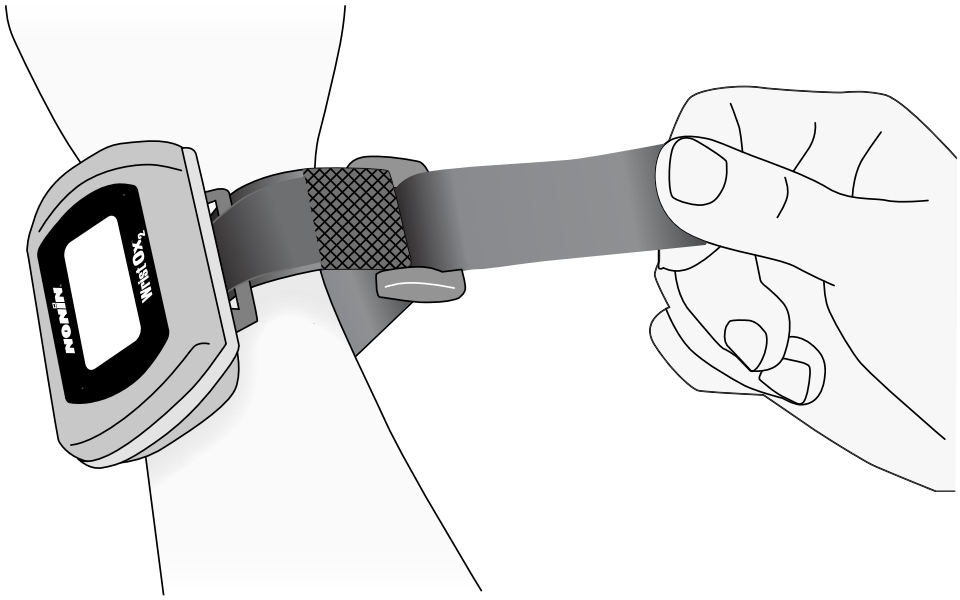


Figure 11: Thread and Tighten Wristband

4. Fold the wristband back over the plastic ring (figure 12) and attach the fastener to the wristband (figure 13 or figure 14). Wrist circumference will determine which fastener is used.

NOTE: When using the rectangle fastener, the end of the wristband can be shortened. To do so, fold the end of the wristband so the square fastener attaches onto the wristband (figure 13).

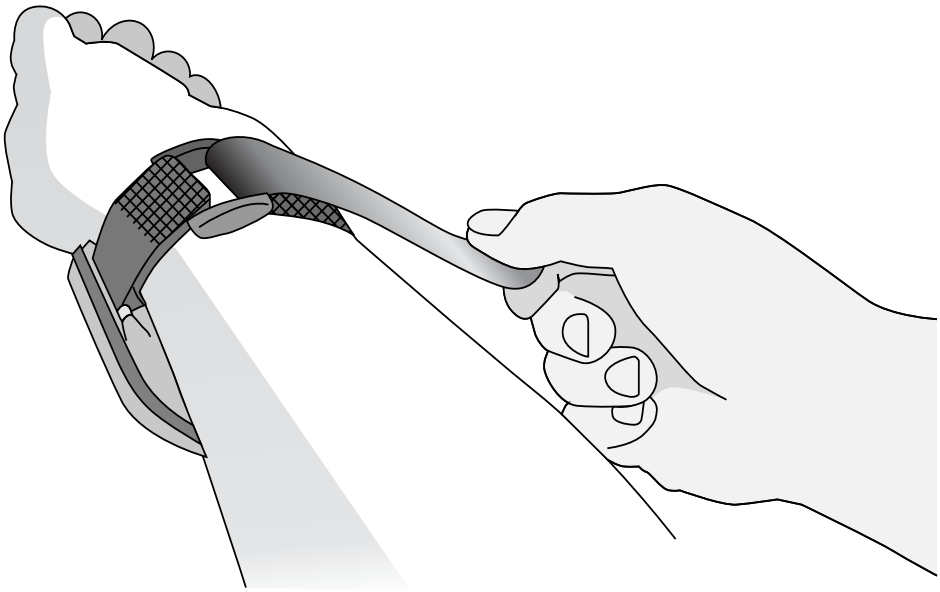


Figure 12: Fasten Wristband

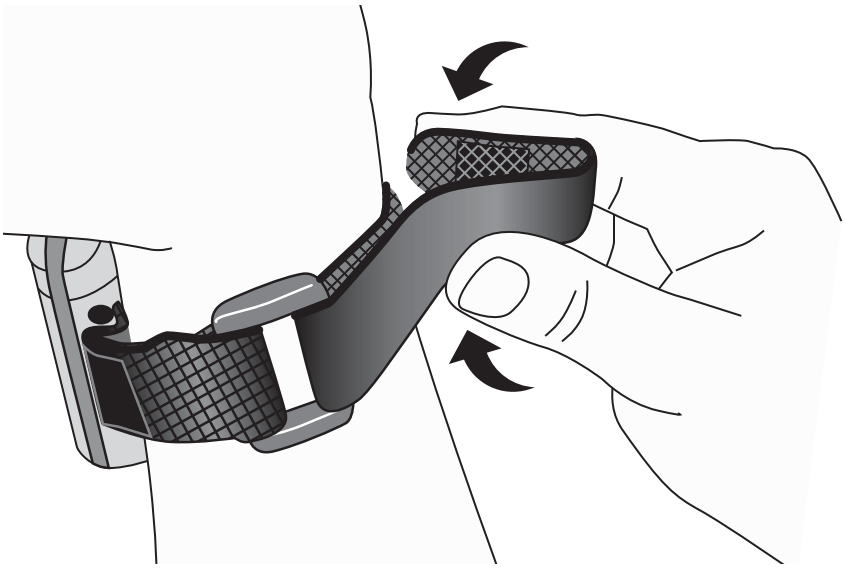


Figure 13: Using the Rectangle Fastener

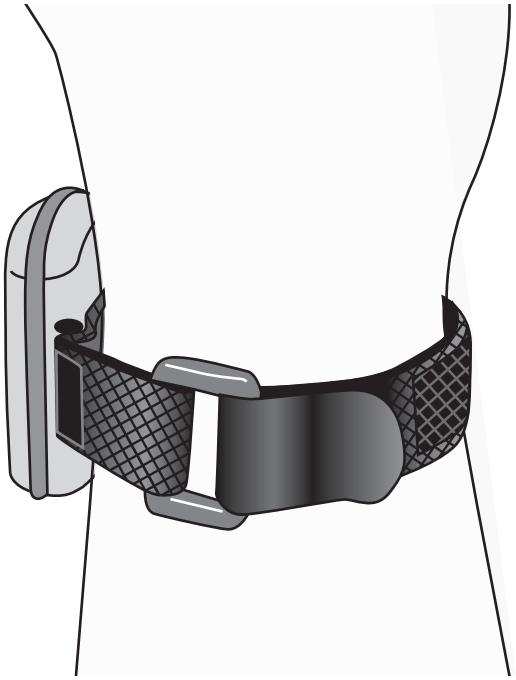


Figure 14: Using the Square Fastener

5. Attach the sensor if it is not already connected (see “Attaching the Sensor”).
6. Apply the sensor to the patient (figure 15). Refer to the sensor Instructions for Use for proper sensor application sites and sensor application cautions and warnings.

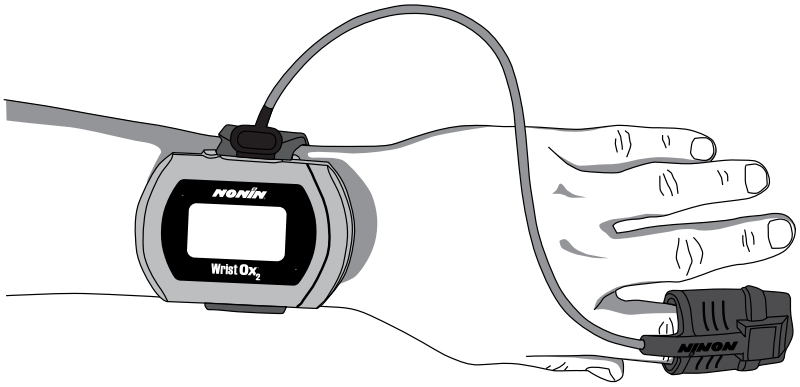


Figure 15: Apply Sensor to Patient

7. When in Spot Check mode, inserting a finger in the sensor automatically turns the device on. When the finger is removed, the device enters Standby mode in approximately 10 seconds.

NOTE: Depending on the sensor and ambient light conditions, it may take up to 3 minutes for the device to enter Standby mode.

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8. If the device does not turn on, verify battery orientation, operation mode, and sensor connection. Refer to “Troubleshooting” for additional information.

Verifying Operation

When the WristOx$_2$, Model 3150, first turns on, it performs a startup sequence and self-test. It occurs:

- When a sensor is applied to a patient (Spot Check mode).
- When a sensor is attached to the device (Sensor Activation mode).
- At a programmed start time when a sensor is attached to the device (Programmed mode).
- After the activation switch is pressed while the device is in Standby mode.
- After the device disconnects from nVISION (Bluetooth connection only).

Verify all indicators display during the startup sequence. Indicators appear in the following order for 1 second each.

Startup Sequence and Self-Test

1. r and the software revision level:

2. All display icons:

3. Date/time using 24-hour clock format (MM:DD:YY:HH:MM) (example shows 23 April 2010 at 5:57 p.m.):

Month and Day (MM:DD)

Year (YY)

Hour and Minutes (HH:MM)

If the time is not set, the device displays 01:01:10:00:00.

If any indicator does not display, do not use the device. Contact Nonin Technical Service for assistance.

Activation Switch

The activation switch is located next to the sensor port at the top of the WristOx$_2$, Model 3150. It is primarily used to:

- Activate the Bluetooth radio when the device is either on or in Standby.
- Activate the device when it is in Sensor Activation mode so the user does not need to disconnect and reconnect the sensor.

It will also activate the device when it is in Spot Check and Programmed modes.

Activate Bluetooth Radio

When the device's Bluetooth radio is on, a master device can connect to it. If a connection is not made, the Bluetooth radio shuts down.

Pressing the activation switch turns the Bluetooth radio on for 3 minutes. The device will remain on until the Bluetooth radio shuts down. For example, if in Sensor Activation mode, unplugging the sensor will not put the device in Standby.

Activate Device

When in Sensor Activation mode, the device enters Standby mode after 10 minutes without a signal. Pressing the activation switch allows the user to turn the device on without disconnecting and reconnecting the sensor.

Error Codes

This device includes error codes that indicate problems with the unit. When an error occurs, the device displays the letters "Er" and a two-digit code (table 2).

Table 2: Error Codes

Error Code	Description
01	Configuration sector error
02	Patient data pointer error
03	Main memory pointer error (Device memory is intact; however, the most recent session may be missing from the device.)
04	Data format 13 stored packet pointer error
05	Main data format 13 pointer error (Device memory is intact; however, the most recent stored measurement may be missing from the device.)

Some error codes may be corrected by the user. See "Troubleshooting" for more information.

Troubleshooting

Problem	Possible Cause	Possible Solution
Device will not activate.	Batteries inserted wrong.	Check batteries.
	Batteries are depleted.	Replace batteries.
	Sensor is disconnected.	Reconnect sensor.
	Device is in Sensor Activation mode and has timed out.	Press the activation switch.
		Disconnect and then reconnect the sensor.
	Device is in Programmed mode.	Use nVISION software to select Spot Check or Sensor Activation mode.
%SpO_2 and pulse rate do not display.	Device set in Partial Display mode.	Use nVISION software to select Full Display mode. Reconnect sensor.
Poor pulse signal ⃠ indicator displays.	Excessive patient motion.	Reduce patient motion.
Poor pulse signal ⃠ indicator displays and pulse strength ♥))) indicator shows two bars or less.	Inadequate pulse signal.	Reposition or replace sensor, or place sensor on a different finger.
		Remove and reconnect sensor.
	Hands are cold.	Warm sensor application site.
No pulse display on pulse strength bar graph indicator.	Sensor applied incorrectly.	Refer to sensor Instructions for Use for proper sensor application.
	Device needs repair.	Contact Nonin Technical Service.
	Possible interference from blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.).	Reduce or eliminate restriction.
	Reduced circulation due to excess pressure from sensor.	Check sensor alignment, reposition sensor, verify correct sensor size.
	Excessive ambient light.	Shield sensor from light source. Check sensor alignment.
	Sensor applied to polished or artificial nail.	Remove fingernail polish or an artificial nail.
	Sensor Light-Emitting Diode (LED) is not lit.	Contact Nonin Technical Service.

Problem	Possible Cause	Possible Solution
Er 01 displays on LCD.	Device configuration memory failure.	Device reverts to default settings (Spot-Check mode, 4-second sample rate). Use nVISION software to change settings. If error code continues, contact Nonin Technical Service.
Er 02 or 04 displays on LCD.	Device memory failure.	Contact Nonin Technical Service.
Er 03 or 05 displays on LCD.	Device failure. Device memory intact, but device may have lost most recent session or stored data.	If error code continues, contact Nonin Technical Service.
Dashes continually display on LCD.	Sensor malfunction.	Replace sensor with a Nonin-branded sensor.
Device does not record in Programmed mode.	Data collection start and stop times are set incorrectly.	Use nVISION software to program correct start and stop times.
	Clock settings are lost after replacing batteries.	Use nVISION software to reset clock.
Devices will not pair.	Device is out of range.	Verify device is in range while being paired (approximately 100 meters [328 feet] spherical radius).
	Bluetooth radio has timed out.	Press activation switch to turn on Bluetooth radio.
%SpO_2 indicator and the heart in the pulse strength indicator do not display.	Device has been set to Memory Volume (MVI) display mode.	Use nVISION software to configure the device to full or partial display mode.

If these solutions do not correct the problem, please contact Nonin Technical Service at (800) 356-8874 (USA and Canada), + 1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

Care and Maintenance

The device requires no calibration or maintenance other than battery replacement. The device's expected service life is 5 years.

Cleaning the Device

Wipe the device with a soft cloth dampened with a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]). Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result. Dry with a soft cloth, or allow to air dry.

Clean once per week or more frequently if handled by multiple users.

CAUTION: Do not place the WristOx$_2$, Model 3150, in liquid or clean it with agents containing ammonium chloride or isopropyl alcohol.

Cleaning the Sensor

Refer to the sensor Instructions for Use for cleaning information.

Cleaning the Wristband

The wristband is designed for single-patient use. If it needs to be cleaned, hand wash with a mild detergent (see note) in cool water (30 °C/86 °F). Allow to air dry.

Do not machine wash or dry. The wristband will shrink if placed in a dryer.

NOTES:
- Mild detergents, such as hand and dish washing liquid detergents, dissolve dirt and grease. To clean washable surfaces, use in a solution of warm water.
- Replace the wristband if the hook and loop fastener no longer secures the wristband to the device or to the patient.

CAUTION: Use a detergent that is safe for skin and washable surfaces. Most detergents can be high sudsing, so use sparingly. Wipe with a damp, detergent-free cloth to remove residue.

CAUTION: After cleaning the single-patient use wristband, it should only be applied to the same patient; do not apply it to a different patient.

Storing

Store the device within the stated environmental specifications. See "Specifications" for additional information.

Remove the batteries and disconnect the sensor if it is to be stored for more than 1 month.

Memory and Data

The WristOx$_2$, Model 3150 measures, collects, and stores up to 1,080 hours of SpO_2 and pulse rate data with a 4-second data collection rate. Data collected at a 1 or 2-second rate reduces memory capacity to 270 or 540 hours, respectively.

When the memory is full, the device overwrites the oldest existing data with the new data. Each time the device is turned on, data are automatically stored in memory. Data collection of less than 1 minute is not retained in memory.

Each time the device turns on, the current oximeter time and date (if the clock is set properly) are stored in memory to allow quick differentiation of recording sessions. Patient SpO_2 and pulse rate are stored every 4 seconds (default), or every 1 or 2 seconds if programmed using nVISION software. The oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

This device contains non-volatile memory. Removing or replacing batteries does not affect the data stored in memory. Stored data remains in memory until overwritten by newer data or cleared from memory with nVISION software.

NOTE: Downloading data in memory does not clear memory. To clear memory, see “nVISION Settings.”

nVISION Software

Nonin's nVISION software (version 6.3 or greater) works with Microsoft Windows® operating systems. It allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data. The software is required to access the device's additional modes of operation and advanced features.

nVISION Settings

The following WristOx$_2$, Model 3150, settings are programmed using nVISION:

- Date and time – 24-hour clock format
- Display options – allows clinicians to choose the best display option for each patient:
  - Full display shows %SpO$_2$ and pulse rate data
  - Partial display shows pulse strength indicator, but not %SpO$_2$ and pulse rate data
  - MVI (memory volume) display shows pulse strength indicator and volume (hours and minutes) of data stored in memory. %SpO$_2$ and pulse rate readings do not display on the screen.
- Patient data storage (sample) rate – 1, 2, or 4 seconds
- Operation Modes – Sensor Activation, Spot-Checking, and Programmed (see "Activation Options")
- Patient ID – up to 50 alphanumeric characters
- Bluetooth Radio – disable at startup
- Synchronize device time/date to the PC time/date
- Download and save patient data to a PC
- Clear device memory

To access nVISION settings, connect the device to a PC using either the PC USB interface cable or a Bluetooth connection.

Accessing nVISION Settings

1. Connect the device to a PC using the USB interface cable (see "Cable Connection") or Bluetooth (see "Bluetooth Connection").

NOTE: If using Windows 2000, the WristOx$_2$, Model 3150 will only connect to a PC with a Bluetooth connection. Windows 2000 does not function with the USB interface cable.

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2. Open nVISION.
3. Click the **Data Capture** icon, or select **New Data Capture** from the File drop down menu.
4. Select **3150** from the list of oximeters.
5. Click **Settings**.
6. "Enter Wrist Oximeter Settings" window opens (figure 16). Update or change settings as needed.
7. Click **OK**.

8. For more information, see nVISION Help.

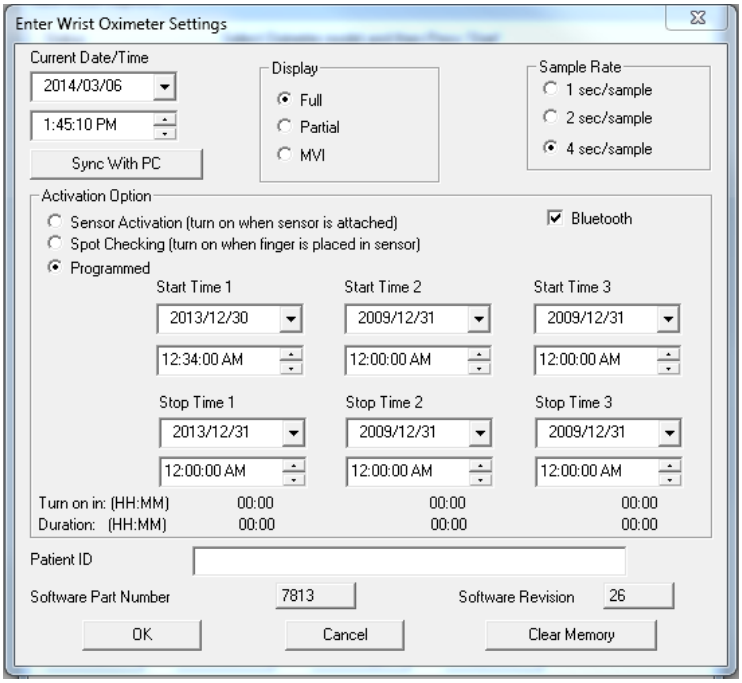

Figure 16: nVISION Settings Window

Cable Connection

NOTE: To save battery life, the Model 3150 will automatically shut off after 60 minutes when it is connected to a PC using the USB interface cable.

To connect the device to a PC, use the PC USB interface cable found in the starter kit. Once connected to a PC, the device settings may be accessed and data can be downloaded using nVISION software.

The USB driver software for the cable needs to be installed before the device can connect to the PC. The software is located in the USB Driver folder on the Operator's Manual CD.

1. Install USB driver if needed. See appropriate "USB Driver Installation" section for more information.
2. Connect the cable to the USB port on the PC.
3. Connect the cable to the device's sensor port.
4. When the device is ready to use with nVISION, these indicators display on the LCD:
   - CP
   - Battery indicator

5. For more information about nVISION, refer to nVISION Help.

NOTE: Disconnect the USB interface cable from the device when the data transfer or device configuration is complete. Leaving the cable connected will reduce battery life.

USB Driver Installation (Windows 7)

1. The USB driver software is on the Model 3150 Operator's Manual CD. Insert the CD into the PC's CD/DVD drive.
2. Connect the Model 31501SC USB cable to the sensor port on the Model 3150 and a USB port on the PC.
3. Open the Device Manager by clicking **Start / Control Panel / System** and then selecting Device Manager.
4. Expand **Other devices**.
5. Right click **Model 3150** and select **Update Driver Software...**
6. Update Driver Software - Model 3150 window opens. Choose **Browse my computer for driver software**.
7. Browse to the USB Driver folder on the Operator's Manual CD and click **OK**.
8. Click **Next**.
9. In the Windows Security pop-up window, select **Install this driver software anyway**.
10. Driver software installs. When Windows has successfully updated the driver software, click **Close**.
11. In the Device Manager window, look up the communications (comm or COM) port for the device. Expand **Ports (COM & LPT)**. One port should say "Nonin Model 3150 (COM#)." Make a note of the COM#. It is needed to set up the Model 3150 with nVISION software.

USB Driver Installation (Windows 8)

1. The USB driver software is on the Model 3150 Operator's Manual CD. Insert the CD into the PC's CD/DVD drive.
2. Connect the Model 3150SC USB cable to the sensor port on the Model 3150 and a USB port on the PC.
3. Open the Device Manager by right clicking in the bottom left corner of the screen and then click **Device Manager**. Device Manager window opens.
4. If needed, expand **Other devices**.
5. Right click **Model 3150** and select **Update Driver Software...**
6. Update Driver Software - Model 3150 window opens. Choose **Browse my computer for driver software**.
7. Browse to the USB Driver folder on the Operator's Manual CD and click **Next**. Verify that "Include subfolders" is checked.
8. In the Windows Security pop-up window, check "Always trust software from Nonin Medical, Inc." and then click **Install**.
9. Driver software installs. When Windows has successfully updated the driver software, click **Close**.
10. In the Device Manager window, look up the communications (comm or COM) port for the device. Expand **Ports (COM & LPT)**. One port should say "Nonin Model 3150 (COM#)." Make a note of the COM#. It is needed to set up the Model 3150 with nVISION software.

USB Driver Installation (Windows 10)

1. The USB driver software is on the Model 3150 Operator's Manual CD. Insert the CD into the PC's CD/DVD drive.
2. Connect the Model 3150SC USB cable to the sensor port on the Model 3150 and a USB port on the PC.
3. Type **Device Manager** in the taskbar's search box, then select Device Manager from the list of results. Device Manager window opens.
4. If needed, expand **Other devices**.
5. Right click **Model 3150** and select **Update Driver Software...**
6. Update Driver Software - Model 3150 window opens. Choose **Browse my computer for driver software**.
7. Browse to the USB Driver folder on the Operator's Manual CD and click **Next**. Verify that "Include subfolders" is checked. **NOTE:** If the Windows Security pop-up window displays, check "Always trust software from Nonin Medical, Inc." and then click **Install**.
8. Driver software installs. When Windows has successfully updated the driver software, click **Close**.
9. In the Device Manager window, look up the communications (comm or COM) port for the device. Expand **Ports (COM & LPT)**. One port should say "Nonin Model 3150 (COM#)." Make a note of the COM#. It is needed to set up the Model 3150 with nVISION software.

Bluetooth Connection

NOTE: Etched onto the device is the word "pin" followed by a 6-digit number. This is the device's unique identification number, also known as the Bluetooth Passkey or PIN Code. This number is used when pairing the device to the host system. Refer to the host system's operator's manual for additional information.

Before a Bluetooth master device can connect with the WristOx$_2$, Model 3150 (slave device), the devices must be paired. Once paired, the WristOx$_2$, Model 3150, will automatically connect with the last paired master device when turned on or activated.

1. To connect the WristOx$_2$, Model 3150, to a PC or another device using Bluetooth, see Nonin's online Bluetooth Connection Tutorial:

   http://www.nonin.com/training/products/3150/bluetooth_connection_tutorial/

2. When nVISION connects to the WristOx$_2$, Model 3150, the device stops recording patient data and the following indicators display on the LCD:
   - CP
   - Battery indicator
   - Bluetooth icon with animated bars

3. For more information about nVISION, refer to nVISION Help.

Bluetooth Security

The Bluetooth radio contained in the 3150 is compliant to version 2.0 of the Bluetooth Specification. It supports the Serial Port Protocol (SPP) and the Health Device Profile (HDP) with security mode 2 (service level enforced). The supported encryption key size is up to 128 bits and encryption is enforced on all outgoing and incoming data channels. While the 3150 is in a Bluetooth connection, it will be unavailable for other connections.

Bluetooth Profiles Supported:	Serial Port Profile (SPP), Health Device Profile (HDP)
Security Mode:	Mode 2 (service-level enforced security)
Authentication and Encryption:	Enforced on all data channels (outgoing and incoming)
Encryption Key Size:	Up to 128 bits

Connecting the Device into a Medical System

Incorporating the device into a medical system requires the integrator to identify, analyze, and evaluate the risks to patient, operators, and third parties. Subsequent changes to the medical system after device integration could introduce new risks and will require additional analysis. Changes to the medical system that must be evaluated include:

- Changing the system configuration
- Adding devices to or disconnecting devices from the system
- Updating or upgrading equipment connected to the system

Issues resulting from user-initiated system changes may include corruption or loss of data.

NOTES:
- When using the sensor port to connect the device to other equipment, follow each device's cleaning instructions.
- Verify all equipment connected to the device is suitable for the patient's environment.

CAUTION: Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.

Parts and Accessories

For more information about Nonin parts, accessories, and sensors, contact your distributor, or contact Nonin at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe). This information is also available on Nonin's website: www.nonin.com.

Model Number	Description
3100CC	Carrying Case
3150 Manual	CD with Operator's Manual and USB Driver Software
3150SC	PC USB Interface Cable
nVISION	nVISION Software (version 6.3 or greater). Used with Microsoft Windows operating systems.
3150I	Sensor Interface Cable. Used to connect 1-meter, 9-pin connector sensors to the WristOx$_2$, Model 3150. For compatible 1-meter sensors, see below, contact Nonin or your distributor, or visit www.nonin.com.
3150WB	Wristband
3100WBE	Wristband Extender, 5 in. (13 cm)

Sensors

WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.

Model Number	Description
Reusable Pulse Oximeter Sensors – 12 inch (0.3 meter) length	
8000AA-WO2	Adult Articulated Finger Clip Sensor
8000J-WO2	Adult Flex Sensor
8000SS-WO2	Soft Sensor Small
8000SM-WO2	Soft Sensor Medium
8000SL-WO2	Soft Sensor Large

Model Number	Description
Optional Pulse Oximeter Sensors (use with Interface Cable 3150I)	
Reusable – 1 meter length	
8000AA	Adult Articulated Finger Clip Sensor
8000AP	Pediatric Finger Clip Sensor
8000Q2	Ear Clip Sensor
8000R	Reflectance Sensor
8000H	Reflectance Sensor Holder
8000SS	Soft Sensor (small)
8000SM	Soft Sensor (medium)
8000SL	Soft Sensor (large)
8000J / 8000JFW	Adult Flex Reusable Sensor / FlexiWrap® Single-Use Sensor Wrap
Disposable – 1 meter length	
6000 Series	Disposable Sensors
6000CA	Adult
6000CP	Pediatric
7000 Series	Flexi-Form® III Single-Patient Use Sensors
7000A	Adult
7000P	Pediatric
6500MA	Adult/Pediatric
6500SA	Adult/Pediatric

Service, Support, and Warranty

Service and Support

For information about the device and accessories, contact your local sales representative or distributor. For the sales representative or distributor in your area, contact Nonin.

A return authorization number is required before returning any product to Nonin. To obtain this return authorization number, contact Nonin's Technical Service Department at:

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, Minnesota 55441-5443 USA

(800) 356-8874 (USA and Canada)
+ 1 (763) 553-9968
Fax: + 1 (763) 553-7807
E-mail: technicalservice@nonin.com

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1075 BD Amsterdam, Netherlands

+31 (0)13 - 79 99 040 (Europe)
Fax: +31 (0)13 - 79 99 042
E-mail: technicalserviceintl@nonin.com

nonin.com

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser the Model 3150, WristOx$_2$ Pulse Oximeter for 3 years from the date of purchase. Nonin shall repair or replace any WristOx$_2$, Model 3150, found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any WristOx$_2$, Model 3150, delivered to the purchaser that is found to be defective in any manner, whether such remedies be in contract, tort, or by law.

This warranty excludes cost of delivery to and from Nonin. All repaired units shall be received by the purchaser at Nonin's place of business. Nonin reserves the right to charge a fee for a warranty repair request on any unit found to be within specifications.

The WristOx$_2$, Model 3150, is a precision electronic instrument and must be repaired by knowledgeable and specially trained Nonin personnel only. Accordingly, any sign or evidence of opening the WristOx$_2$, Model 3150, field service by non-Nonin personnel, tampering, or any kind of misuse of the WristOx$_2$, Model 3150, shall void the warranty.

All non-warranty work shall be performed according to Nonin standard rates and charges in effect at the time of delivery to Nonin.

DISCLAIMER/EXCLUSIVITY OF WARRANTY:

THE WARRANTIES IN THIS MANUAL ARE EXCLUSIVE, AND NO OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, OR IMPLIED, SHALL APPLY.

Technical Information

NOTE: This product complies with ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

CAUTION: A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.

Manufacturer's Declaration

Refer to the following table for specific information regarding this device's compliance to IEC 60601-1-2.

Table 3: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 2	This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Table 4: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage before application of the test level.			

Table 5: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 3 V/m	80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$ where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the symbol: 
NOTES: 1. At 80 MHz and 800 MHz, the higher frequency range applies. 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6: Recommended Separation Distances

This table details the recommended separation distances between portable and mobile RF communications equipment and this device

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.

	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.2	1.2	2.3
10	3.7	3.7	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

1. At 80 MHz and 800 MHz, the higher frequency range applies.

2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Equipment Response Time

If the signal from the sensor is inadequate, the last measured SpO_2 and pulse rate values freeze for 10 seconds and are then replaced with dashes.

SpO_2 Values	**Average**	**Latency**
Standard/Fast Averaged SpO_2	4 beat exponential	2 beats

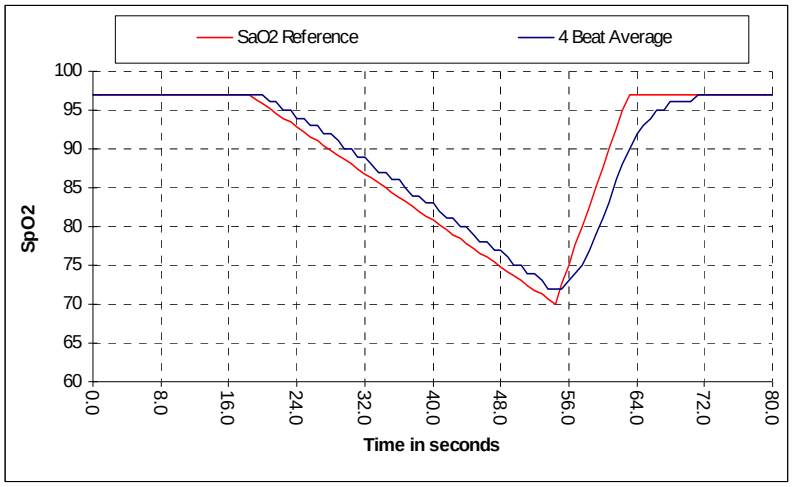
Pulse Rate Values	**Response**	**Latency**
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats

Equipment Delays	**Delay**
Display Update Delay	1.5 seconds

Example - SpO_2 Exponential Averaging

SpO_2 decreases 0.75% per second (7.5% over 10 seconds)

Pulse Rate = 75 BPM



Specific to this example:

- The response of the 4-beat average is 1.5 seconds.

Testing Summary

SpO_2 accuracy and low perfusion testing was conducted by Nonin Medical, Inc., as described below.

SpO_2 Accuracy Testing

During motion and no-motion conditions at an independent research laboratory, SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, male and female, non-smoking, light- to dark-skinned subjects that are 18 years of age and older. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Pulse Rate Motion Testing

This test measures pulse rate oximeter accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 80601-2-61 for pulse rate during simulated movement, tremor, and spike motions.

Low Perfusion Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

Principles of Operation

Pulse oximetry is a non-invasive method that passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) from this color difference by measuring the ratio of absorbed red and infrared light as volume fluctuates with each pulse.

Specifications

Oximeter Specifications

Oxygen Saturation Display Range:	0 to 100 % SpO_2
Pulse Rate Display Range:	18 to 321 beats per minute (BPM)
Displays:	
Numeric:	3-digit LCD
Pulse Strength:	Pulse Strength Bar Graph
Accuracy – Sensors:	Declared accuracy data for compatible sensors can be found in Nonin's Sensor Accuracy document.
Measurement Wavelengths and Output Power[a]:	
Red:	660 nanometers @ 0.8 mW max. avg.
Infrared:	910 nanometers @ 1.2 mW max. avg.

a.This information is especially useful for clinicians performing photodynamic therapy.

System Specifications

Temperature:	
Operating:	-5 °C to 40 °C (23 °F to 104 °F)
Storage/Transportation:	-40 °C to 70 °C (40 °F to 158 °F)
Time (from storage) for monitor to be ready for its intended use:	10 minutes to warm from -40 °C to -5 °C 10 minutes to cool from 70 °C to 40 °C
Device temperature will not exceed 41°C as measured during a controlled environment test.	
Humidity:	
Operating:	10 % to 95 % noncondensing
Storage/Transportation:	10 % to 95 % noncondensing
Operating Altitude:	Up to 4,000 meters (13,123 feet)
Operating Hyperbaric Pressure:	Up to 4 atmospheres

Power Requirements:	Two AAA (1.5V) batteries		
Battery Life (expected minimum): **NOTE:** Based on testing new and fully-charged batteries. See footnotes for brands used. Refer to battery manufacturers' operator's manuals for instructions for use.	**Alkaline AAA[a]**	**Rechargeable AAA (700 mAh)[b]**	**Rechargeable AAA (1100 mAh)[c]**
Storage: MVI display mode off: MVI display mode on:	9 months 25 days	Not specified	Not specified
Operating without Bluetooth, continuous use:	53 hours	36 hours	55 hours
Operating at 100 m (Bluetooth Class 1[d]), continuous use:	19 hours	15 hours	24 hours
Operating at 10 m (Bluetooth Class 2), continuous use:	21 hours	16 hours	24 hours
Dimensions (without sensor or wristband):	51 mm x 73 mm x 19 mm (H x W x D) (2.0 in. x 2.9 in. x 0.75 in.)		
Weight (with batteries and wristband):	70.0 g (2.5 oz)		
Memory:			
Type:	Non-volatile		
Capacity:	up to 1,080 hours (4 sec. data storage rate) up to 540 hours (2 sec. data storage rate) up to 270 hours (1 sec. data storage rate)		
Classification per ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1:			
Type of Protection:	Internally powered (battery power)		
Degree of Protection:	Type BF-Applied Part		
Mode of Operation:	Continuous		
Enclosure Degree of Ingress Protection:	IP33		
This product complies with ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing.			

a.Batteries used: Harding Model LR03 Alkaline AAA

b.Batteries used: Energizer Recharge® Power Plus Model NH12BP NiMH AAA
Charger used: Energizer Model CH15MN2

c.Batteries used: Ansmann Model 5035232 NiMH AAA
Charger used: Ansmann PL 8 Model AN12510

d. When operating with Bluetooth, typical battery life may vary depending on proximity to host connection and configuration of host-to-device communications. Times provided are minimum times for common configurations.

Transmitter

Bluetooth Compliance:	Version 2.0
Operating Frequency:	2.4 to 2.4835 GHz
Output Power:	< 20 dBm
Operating Range:	100-meter (328-foot) radius indoors
Network Topology:	Point-to-Point
Operation:	Slave
Antenna Type:	Internal
Modulation Type:	Frequency Shift Keying Frequency Hopping Spread Spectrum
Band Width:	1 MHz

EXHIBIT 3

User Guide

nVISION®

Pulse Oximetry
Data Management Software

Version 6.4

CE 0123

English

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9839-001-02

Contents

nVISION Software

Nonin's nVISION® software provides a convenient user interface for capturing, editing, storing, analyzing, and printing patient data from many Nonin pulse oximeters.

nVISION enables users of Nonin pulse oximeters to capture (download) patient data during memory playback by reading the serial communications port and then saving the data to a disk file on a PC with a Windows® XP SP3, Vista, 7 (32 bit and 64 bit), or 8 (32 bit and 64 bit) operating system. nVISION also enables users to review, analyze, and edit saved data sets and to print reports.

NOTE: Do not use nVISION data as the sole basis for making a medical diagnosis!

Remarque : Ne basez pas votre diagnostic médical uniquement sur les données de nVISION !

Hinweis: Zum Stellen einer medizinischen Diagnose dürfen nVISION-Daten nicht als ausschließliche Grundlage verwendet werden!

Nota: Non usare i dati nVISION come unica base per la diagnosi medica.

Nota: No utilice la información de nVISION como única base para realizar un diagnóstico médico.

Observação: Não utilize os dados do nVISION como base exclusiva para estabelecer um diagnóstico médico!

NB: Gebruik de gegevens van nVISION niet als de enige basis voor een medische diagnose!

Obs! Data från nVISION skall ej användas som enda underlag för medicinska diagnoser!

Bemærk: Brug ikke nVISION data som eneste grundlag for at stille medicinsk diagnose!

See Also:

Overview of nVISION
Getting Help With nVISION
Computer Requirements
System Setup
Installing and Uninstalling nVISION Software
Using the Glossary
Capturing and Saving Data
Tutorial

Overview of nVISION

The topics listed in this overview describe the basic features of nVISION and explain how the software works. The organization of this overview follows the order in which the topics are displayed in the nVISION Help Table of Contents. Click on the underlined topics for detailed information.

NOTE: Review the Tutorial section for a detailed demonstration of nVISION software.

Using nVISION Online Help

This section provides the steps required for effectively using nVISION Help.

Getting Help With nVISION
Printing Help Topics
Using the Glossary

Getting Started

This section provides computer and system setup requirements, software installation instructions, and a setup and use quick tour.

Computer Requirements
Installing and Uninstalling nVISION Software
System Setup
Setup and Use Quick Tour

Toolbar and Menus

This section provides detailed information about the nVISION toolbar and pull-down menu commands.

nVISION Toolbar
File Menu Commands
Edit Menu Commands
Options Menu Commands
Report Menu Commands
Help Menu Commands

Capturing and Saving Data

This section provides detailed instructions on downloading data from a pulse oximeter and saving the data set on a PC.

Capturing and Saving Data

Data Analysis

This section provides instructions for setting display and analysis parameters and for editing and analyzing patient data.

Editing Data
Analyzing Data

Data Reports

This section provides instructions for setting report parameters and printing reports.

Report Descriptions
Printing Reports

Tutorial

This section is intended to help you become familiar with nVISION software by walking you through the downloading and analysis of a practice data set.

Tutorial

Glossary of Terms

This section contains definitions of terms as well as graphics and other useful information.

Using the Glossary

FAQs (Frequently Asked Questions)

This section provides answers to common questions about nVISION software.

FAQs

Customer Support

This section provides detailed information on contacting Nonin Customer Support.

Customer Support

Symbols

Symbol	Description
	Follow instructions for use.
	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
	Authorized Representative in the European Community.
	Medical prescription required

See Also:

nVISION Software

Getting Help with nVISION

Nonin nVISION software comes with an online Help System to help you understand and use the software. A Glossary of Terms is also included in the Help System.

To Use nVISION Help:

1. Select Help Topics from the Help menu.
2. Choose the Contents tab to review the table of contents

-or-

choose the Index tab to search the index entries

-or-

choose the Find tab to search for a specific word or words (a full-text search) in the Help Topics.

See Also:

Printing Help Topics
Help Menu Commands
Using the Glossary
Contacting Customer Support

Printing Help Topics

You can print Help Topics using any of the methods listed below.

To Print Help Topics:

- Press the Print button at the bottom of the Help Topics Contents tab:
  - To print an entire book (section) from the Help Table of Contents, highlight (choose) the book and then press the Print button at the bottom of the Help Topics Content tab.
  - To print an individual topic, highlight (choose) the topic and press the Print button at the bottom of the Help Topics Contents tab.

-or-

- Press the Print button at the top of any open Help Topic window.

-or-

- Select the Print Topic command from the File menu of any open Help Topic window.

-or-

- Right-click (use the right mouse button), and choose “Print Topic” when any Help Topic or popup window is open.

The Print dialog box appears when any of these printing methods is used.

Tip! You can copy text (without the graphics) in any open Help Topic or popup window. Select Copy from the menu that appears when you right-click any open Help topic or popup window.

See Also:

Getting Help With nVISION
Using the Glossary

Using the Glossary of Terms

To Find Terms in the Glossary:

1. Click the Glossary button at the top of any open Help Topic window, or choose Glossary of Terms from the Help system Table of Contents. The Help Glossary of Terms window appears.
2. Scroll through the glossary, or click on the alphabetized buttons at the top of the Glossary of Terms window to choose the desired glossary term.

To Print a Definition from the Glossary of Terms:

1. Select the glossary term by left-clicking once on the underlined glossary text. A popup window with a definition, graphic, or other information appears (just like the one that appears when you left-click on the previous underlined words).
2. Right-click once on the popup window. A menu appears.
3. Choose Print Topic. The print dialog box appears.
4. Make your print selection.
5. Left-click anywhere on the screen to close the popup window.

 **Tip!** You can copy text (without the graphics) in any open Help Topic or popup window. Choose Copy from the menu that appears when you right-click any open Help topic or popup window.

See Also:

Getting Help With nVISION
Printing Help Topics

Getting Started

Computer Requirements

Nonin nVISION software is a 32-bit application that will operate on a host computer that meets the following minimum requirements:

- IBM-compatible PC with a 133 MHz Pentium microprocessor or equivalent
- Windows XP SP3, Windows Vista, Windows 7 (32 bit and 64 bit) or Windows 8 (32 bit and 64 bit) operating systems
- At least 256Mb of RAM (memory)
- At least 20Mb free space on the hard drive
- CD-ROM drive (24X speed)
- Video card with 800 x600 VGA resolution
- At least 1 serial communications port

NOTE: Be sure to read the "ReadMe.txt" file on the nVISION CD-ROM for any late-breaking information about nVISION software.

See Also:

Installing and Uninstalling nVISION Software
System Setup
Setup and Use Quick Tour

Installing and Uninstalling nVISION Software

Instructions for installing nVISION software are printed on the nVISION CD-ROM jacket. The nVISION software installation instructions are also included below for reference and can be printed if desired.

You can install, uninstall, and reinstall nVISION software using the standard Windows "Add/Remove Programs" application found in the Windows Control Panel pull-down menu. During the installation process, the install program will ask for a key code. The installation will not proceed if an invalid key code is entered. (When calling Nonin Customer Support, you will be asked to provide this key code.)

NOTE: Before beginning nVISION software installation, ensure that the PC meets the minimum system requirements.

NOTE: When installing nVISION, any version currently installed will automatically be overwritten.

To Install nVISION Software

1. Insert the nVISION CD into the CD-ROM drive with the label facing upward.
2. The install will start automatically. Follow the on-screen instructions until the installation is complete.
3. Click on Start.
4. Point to Programs.
5. Go to the nVISION entry and click on the nVISION program icon .

NOTE: After nVISION is running, use the nVISION online Help system for instructions on using nVISION software.

To Uninstall nVISION Software

1. Start the "Add/Remove Programs" application found in the Windows Control Panel pull-down menu.
2. Scroll through the list and highlight nVISION.
3. Answer "yes" to the questions regarding files to be removed.
4. Follow the on-screen instructions for uninstalling the program.

To Reinstall nVISION Software

See "To Install nVISION software" above.

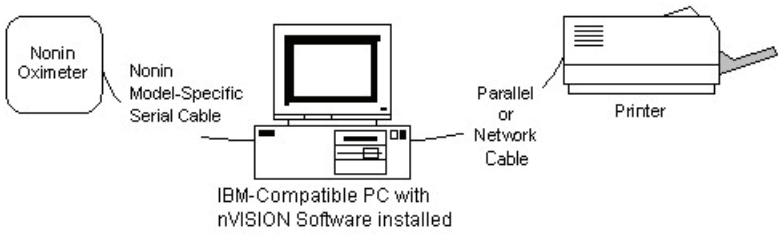
See Also:

Computer Requirements
System Setup
Setup and Use Quick Tour

System Setup

nVISION software is one part of an integrated system consisting of a Nonin pulse oximeter, the appropriate Nonin serial cable, a PC and PC monitor, nVISION software, the appropriate parallel cable or network connection, and a printer.

The following diagram depicts the relationship of the components in the system:



nVISION software is compatible with most Nonin pulse oximeters that store data into memory, as well as the TrendSense memory module.

NOTES:

- Nonin serial cables are necessary for downloading unless the oximeter has a Bluetooth capability.
- In order for stored data to correlate to a 24-hour clock (international time), the time and date must be set in the pulse oximeter before recording patient data. If time and date are not set in the pulse oximeter before recording patient data, nVISION will automatically assign the time set in the PC at the time of download as the study time.
- nVISION is not a networked application.

See Also:

Computer Requirements
Installing and Uninstalling nVISION Software
Setup and Use Quick Tour
Capturing and Saving Data
Comm Port

Setup and Use Quick Tour

Follow these steps for a quick tour of nVISION software:

1. Install nVISION software on the PC.
2. Connect the serial cable between the pulse oximeter and the PC.
3. Set the Report Title and the units of measure.
4. Set the display parameters.
5. Set the analysis parameters.
6. Capture data (download data) or open a saved data set.
7. Edit the data.
8. Analyze the data.
9. Print a report.

See Also:

Overview of nVISION
Computer Requirements
Installing and Uninstalling nVISION Software
System Setup
Capturing and Saving Data
Editing Data
Analyzing Data
Printing Reports
Tutorial

Toolbar and Menus

nVISION Toolbar

The nVISION toolbar provides shortcuts to some frequently used commands. The tools and associated pull-down menu commands are shown below. Click on a command for more information.

File > New Data Capture

File > Open Saved Data

File > Print

File > Print Preview

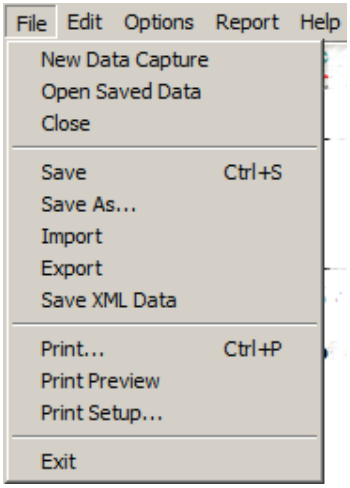
Edit > Summarize Data

Edit > Exclude Data

Options > Display Parameters

Options > Language

File Menu Commands



The following commands appear under the File pull-down menu. Click on a command for more information.

New Data Capture captures data played back from the pulse oximeter.

Open Saved Data opens a saved data set.

Close closes a data set.

Save saves an open data set using the same file name.

Save As saves an open data set to a specified file name.

Import (Importing Data) imports a previously exported nVISION data set as a new data set.

Export (Exporting Data) exports the currently open data set to an ASCII or PDF file.

Save XML Data saves the three XML files associated with the Oximetry Report into the XMLData folder.

Print displays the print dialog box for the current report.

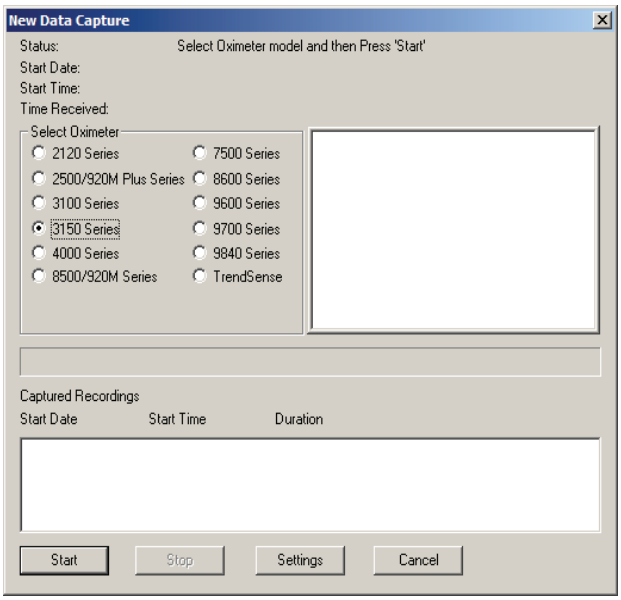
Print Preview displays the report as it would appear if printed.

Print Setup selects a printer and printer connection.

Exit exits nVISION.

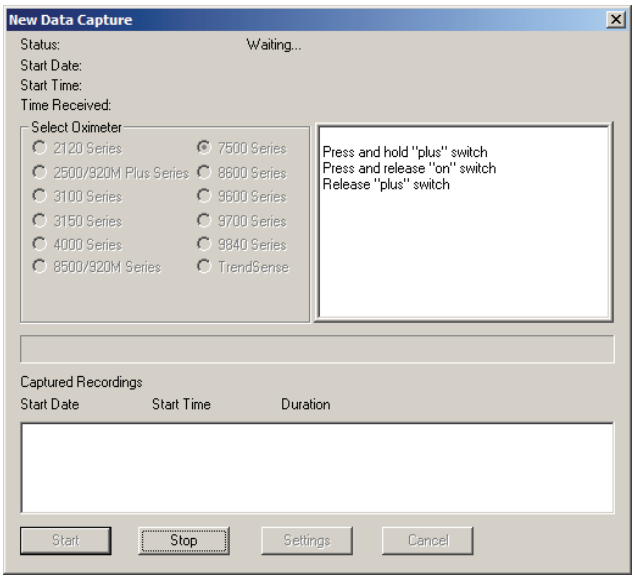
New Data Capture (File Menu)

The nVISION Data Capture feature accepts up to 72 hours of data downloaded from Nonin pulse oximeters. When the New Data Capture command under the File menu is selected or the Data Capture icon on the toolbar is clicked, the New Data Capture dialog box appears:



This dialog box lists the available models of Nonin Pulse Oximeters. Specific instructions for downloading data from the selected pulse oximeter appear in the instruction box. When a different pulse oximeter is selected, the instructions change accordingly. When the user selects any oximeter other than the 3100 or 3150 selection, the Settings button will be disabled. See Capturing and Saving Data for more information about 31XX Settings.

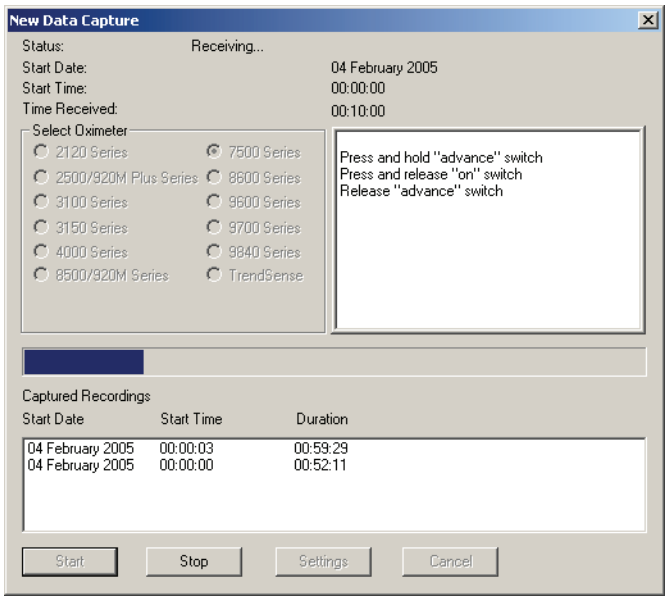
- To capture (download) data, select the appropriate pulse oximeter and press Start. Then follow the directions in the instruction box to initiate the pulse oximeter's Playback mode.
- When Start is selected and the pulse oximeter is in Playback mode, the dialog box changes as shown:



- When Cancel is selected, the dialog box closes.

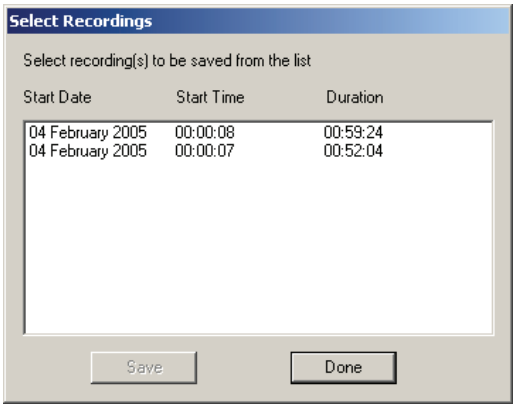
NOTE: When Start is selected and the pulse oximeter is not in Playback mode, the Not In Playback Mode dialog box (not shown) appears and then closes when OK is pressed.

- The Select Oximeter radio buttons and the Start and Cancel buttons are disabled, and the Stop button is enabled.
- The Status changes to “Waiting,” and then to “Receiving” when patient data are received.



- The Start Date and Start Time change to reflect the recording currently being captured.
- The Time Received updates periodically, indicating how many hours of data have been captured for the recording currently being captured.
- The Progress Bar shows the download progress for the recording currently being captured.
- The Captured Recordings dialog box updates as each recording is captured, with the most recent recording shown at the top.

When the Stop command is selected, Data Capture (downloading) terminates. If no complete data sets have been captured, the Main window appears. When at least one complete data set has been captured and/or when all data sets have been captured, the Select Recordings dialog box appears:



NOTE: Depending on the software revision, some 8600 pulse oximeters may not automatically advance to the Select Recordings dialog box after transferring data. If after one minute, nVISION does not advance to the Select Recordings dialog box, click on Stop to proceed to the Select Recordings dialog box.

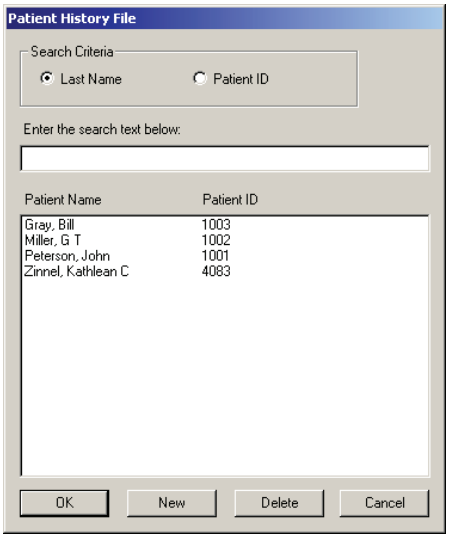
NOTE: When the 3100 or 3150 Wrist Oximeter is used, data sets that have been recorded with different sample rates cannot be merged. This means that as soon as the user selects the first data set, only data sets that have the same sample rates may also be selected.

When Done is selected but not all of the data sets have been saved, the OK to skip remaining recording(s) dialog box appears.

- When No or Cancel is selected, the dialog box closes and the Select Recordings dialog box reappears.
- When Yes is selected, the Main window appears and the remaining recordings are not saved.

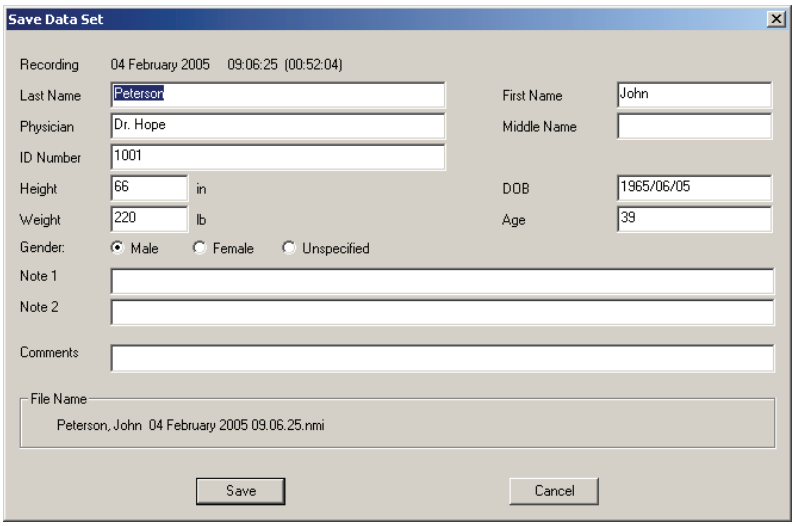
NOTE: You can highlight one or more recordings (click on each entry) from the list in the Captured Recordings dialog box to be saved as a single data set. If the clock was not set, a ten-minute interval appears between datasets. When more than one recording is selected, the time between the recordings will be marked as artifact.

- When Save is selected with the recording(s) highlighted (selected), the Patient History File dialog box appears:

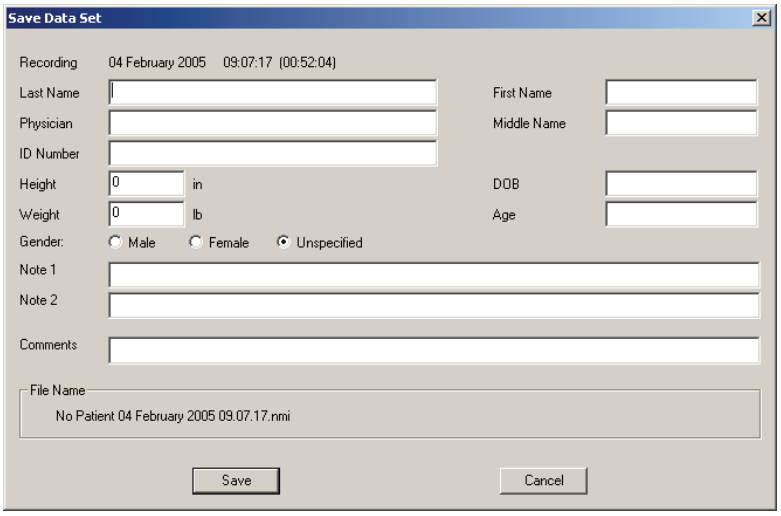


- When Cancel is selected, the Select Recordings dialog box reappears.

When a patient is selected and OK is pressed, the Save Data Set dialog box appears, with information about the selected patient appearing in the dialog box as shown below.



- When New is selected, the Save Data Set dialog box appears with no patient information entered.



Click in each box to enter patient information, or use your computer Tab key to navigate to the next box.

NOTE: You are not required to enter any data in the fields. If you do not enter any patient information and then select Save, the file name will default to "No Patient" and the patient information will remain blank.

NOTE: On an initial download, if the date of birth (DOB) field is filled in, the Age field will be calculated automatically when the Save button is clicked or the cursor is moved to the Age field.

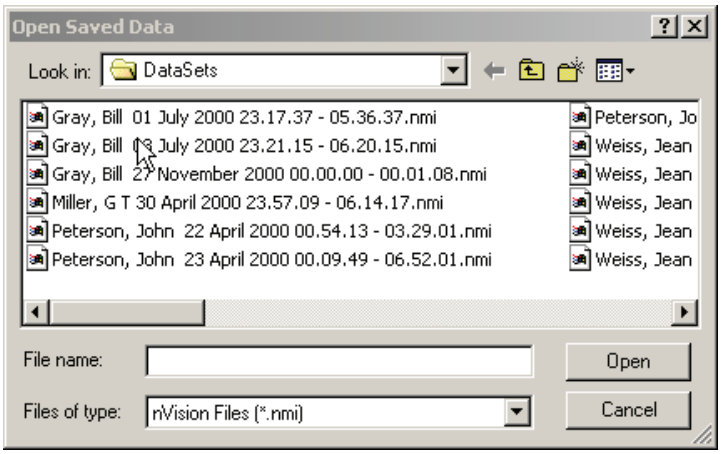
- When Cancel is selected, the Select Recordings dialog box appears if there are still recordings that have not been saved.
- When Save is selected, the data set is saved to a file with the created file name, and the Select Recordings dialog box reappears if there are data sets remaining. The recently-saved data set no longer appears in the dialog box.

The file name for storing the data set is generated from the Name, recording date, and recording time, as shown. You are not allowed to change this generated name at this time. (If you wish to change the name at another time, use the Save As command in the File pull-down menu.)

See Also:
File Menu Commands

Open Saved Data (File Menu)

When the Open Saved Data command under the File pull-down menu is selected or the Open icon on the toolbar is clicked, a list of available data sets appears in a dialog box:



When this dialog box opens, the starting folder is the default data directory (Data Path) selected through the Options menu. The case studies (data sets) are listed in alphabetical order. Use standard Windows buttons to navigate through the directory structure or access the "quick search" function by typing the first few letters of the case study in the File name: box.

When Open is selected, the highlighted data set will appear on the Main window in the Oximetry Report format. Only one data set can be open at any time.

When Cancel is selected, the dialog box closes.

See Also:
File Menu Commands

Close (File Menu)

When the Close command under the File menu is selected, the currently open case closes, the Main Window remains.

See Also:
File Menu Commands

Save (File Menu)

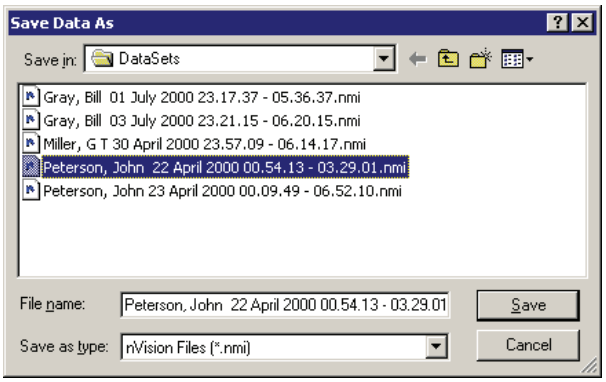
When the Save command under the File menu is selected, the open case and any changes made to it are saved under the same file name, which overwrites the previous data set.

See Also:
File Menu Commands

Save As (File Menu)

The Save As command allows you to save any data set with a different file name. For example, you may choose to perform some specific data editing on an existing data set but not want to modify or overwrite results from a previous analysis. The Save As command allows you to perform modifications to an existing data set and save it with a different file name while maintaining the original data set.

When the Save As command under the File menu is selected, the Save Data As dialog box appears:



When this dialog box appears, users can enter a new file name for the data set. Data sets can be saved in any computer directory, but the default location is set by the user through the (Data Path) command in the Options pull-down menu. The case studies appearing in the Save Data As dialog box are listed in alphabetical order, and standard Windows buttons are available for navigating the directory structure.

The default name created for the new data set is the old file name with a number enclosed in parentheses. The number in parentheses corresponds to the number of data set copies that have been saved. You may use this name or create a different name by typing into the File name box.

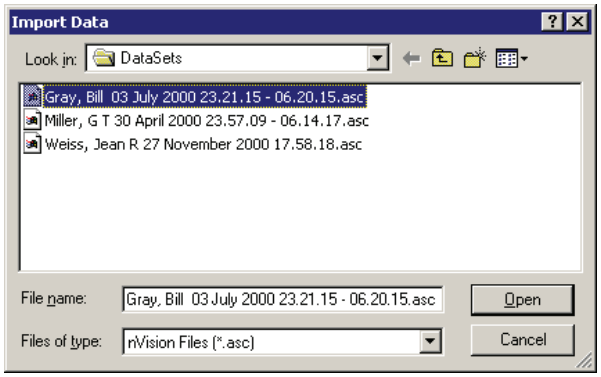
Because only one data set can be open at any time, the data set with the new file name becomes the open data set.

See Also:
File Menu Commands

Importing Data

The Import command allows you to import data that has previously been exported from nVISION. Selecting Import from the File pull-down menu allows you to import an exported data set from an ASCII file into the "DataSets" directory and the Patient History database.

When you select Import from the File pull-down menu, the Import Data dialog box appears:



When the Import Data dialog box is open, the starting folder is the default data directory selected through the

Options pull-down menu and stored in the system registry. The case studies are listed in alphabetical order, and standard Windows buttons are available for navigating through the directory structure.

Use the following procedure to import data to nVISION:

1. Select Import from the File pull-down menu. The Import Data dialog box appears.
2. Locate and click on the data set you want to import.
3. Click the Open button.

Since only one case can be available at a time, importing a case closes the previously opened case. When Cancel is selected, the dialog box closes.

See Also:

Exporting Data
File Menu Commands

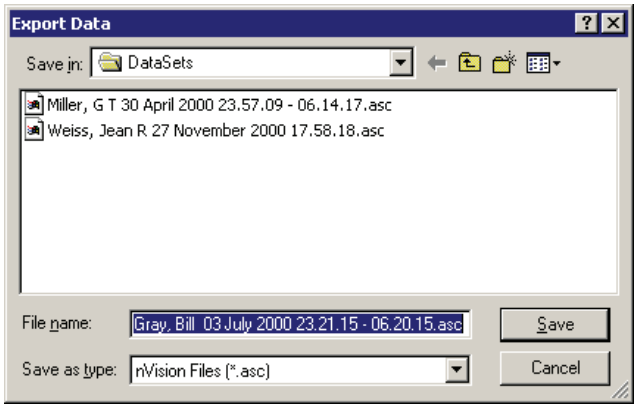
Exporting Data

The Export command allows you to export data from nVISION to a comma delimited file so it can be read into either a spreadsheet program such as Microsoft Excel or as a PDF file. An exported comma delimited case can be emailed to another person who also has nVISION installed on their PC and wishes to view and analyze the data.

Selecting Export from the File pull-down menu allows you to convert a data set from the internal format to a fixed format ASCII character file or a PDF file.

Exported data formats are Patient ID, Year, Month, Day, Hr, Min, Sec, Pulse Rate, %SpO2, and Respiration Rate (if available)—all on the same line but separated by commas. Patient information from the Patient History file precedes data lines in an exported file.

When you select Export from the File pull-down menu, the Export Data dialog box appears:



When the Export Data dialog box is open, the starting folder is the default data directory selected through the Options pull-down menu. The case studies are listed in alphabetical order, and standard Windows buttons are available for navigating the directory structure.

The default name for the new data set is the old name—but with a different extension. You may keep or change this name.

PDF files cannot be read back into nVision.

See Also:

Importing Data
File Menu Commands

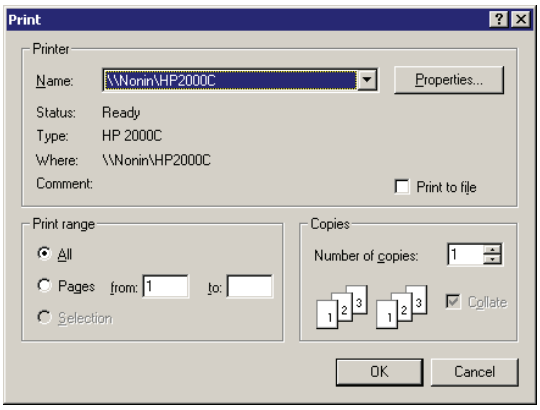
Save XML Data

This command will cause the Oximetry Report data to be saved in an XML file with the same name as the .nmi file the study is saved in. Two other files in a .png format will be saved with the same name plus SpO2 or Pulse added to the name. These are the SpO2 and Pulse graphs which are referenced in the XML file. All three files must remain in the same directory to display properly. This can be opened in Microsoft Internet Explorer or any other XML utility.

The Save XML Data command will be grayed out on all reports except the Oximetry Report. Once the XML files have been saved, they cannot be saved again until the study has been reopened with the Open Saved Data option in the File menu.

Print (File Menu)

When the Print command under the File menu is selected or the Print icon on the toolbar is clicked, the standard Windows Print dialog box will appear, allowing you to print the currently selected report:



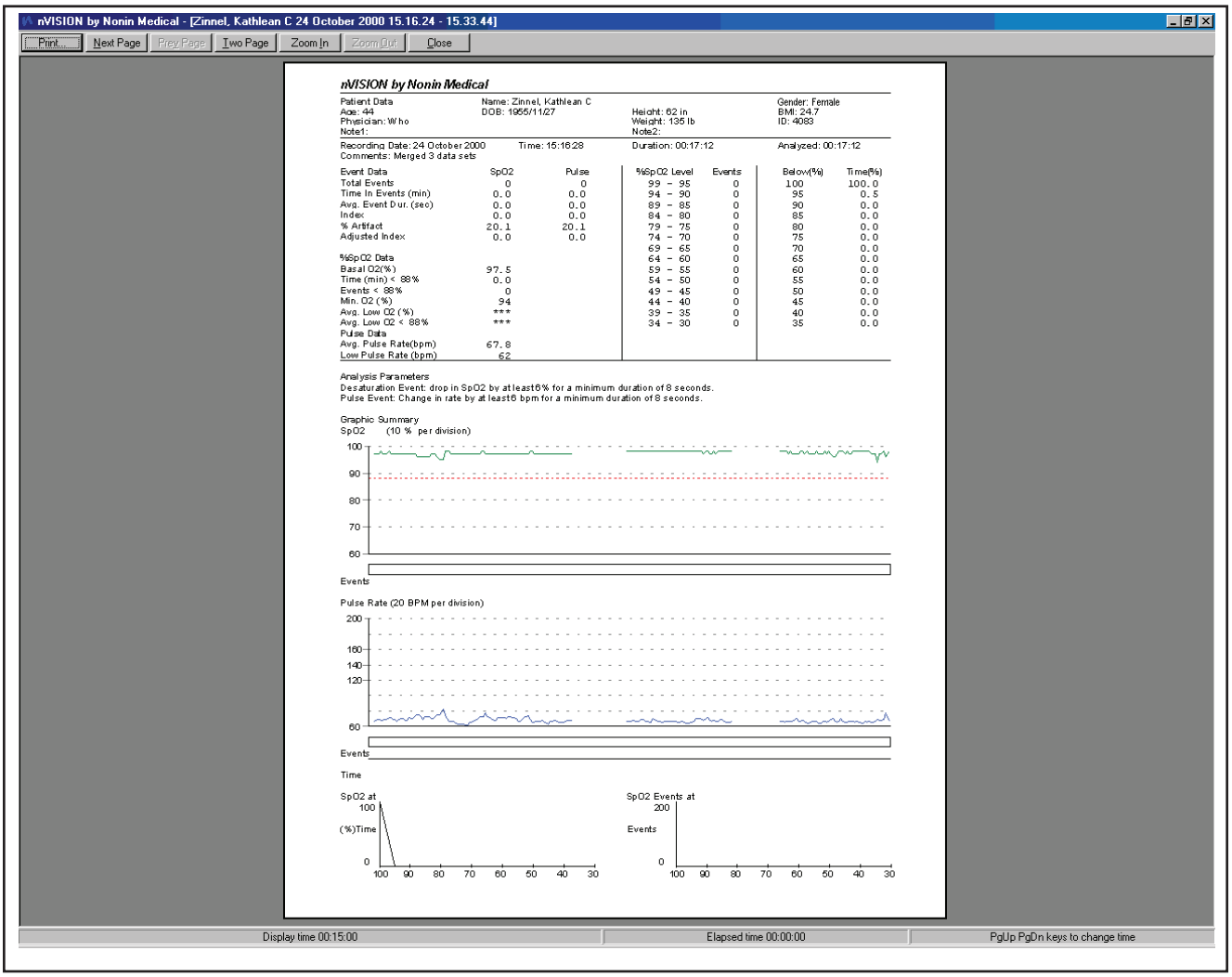
When Cancel is selected, the dialog box closes.

See Also:

File Menu Commands

Print Preview (File Menu)

When the Print Preview command under the File menu is selected or the Print Preview icon on the toolbar is clicked, the report data is displayed as it would appear if printed.



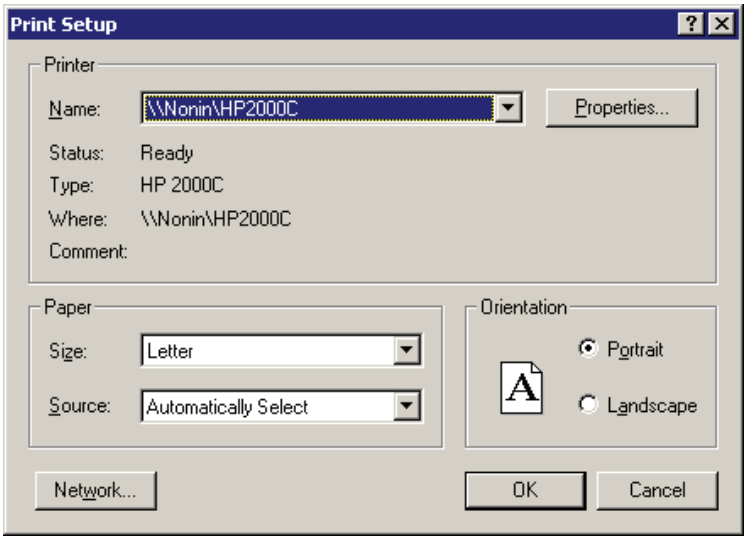
- When Print is selected, the Print dialog box appears.
- The Next Page and Prev Page (previous page) buttons allow you to navigate through the pages when previewing a multi-page report.
- The Two Page button allows you to preview two pages of the report at one time. This button toggles between Two Page and One Page.
- The Zoom In and Zoom Out buttons allow you to zoom in or out when previewing the report.
- When Close is selected, the Print Preview dialog box closes.

See Also:

File Menu Commands

Print Setup (File Menu)

When the Print Setup command under the File menu is selected, the standard Windows Print Setup dialog box appears:



When Cancel is selected, the dialog box closes.

See Also:
File Menu Commands

Exit (File Menu)

When the Exit command under the File menu is selected, the nVISION program terminates.

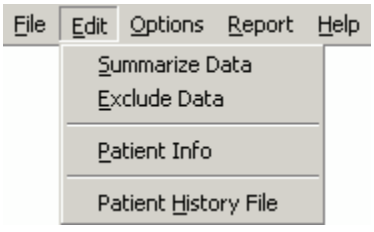
NOTE: No files are saved unless you specifically follow through with the Save or Save As command.

See Also:
File Menu Commands

Edit Menu Commands

The following commands appear under the Edit menu. Click on a command for more information.

- Summarize Data
- Exclude Data
- Patient Info
- Patient History File



Summarize Data (Edit Menu)

The Summarize Data command is under the Edit menu. This command is only available when the Strip Chart Report is active and when an area of interest on a Strip Chart Report is selected using the mouse.

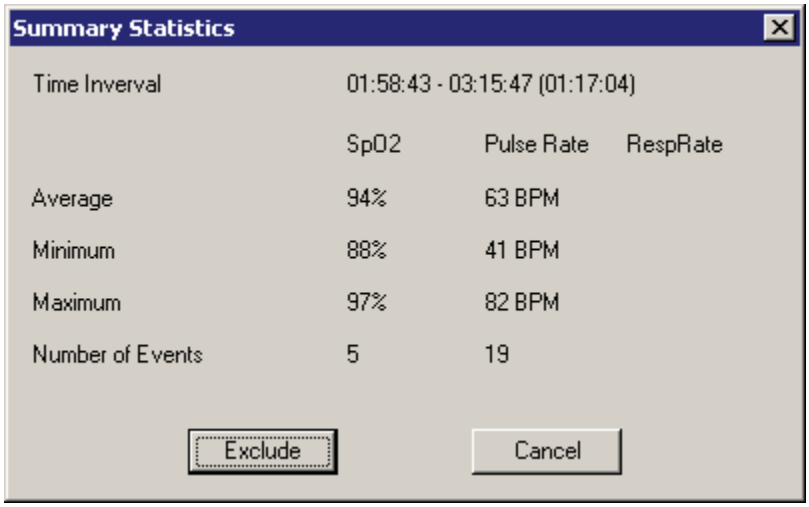
To Select an Area of Interest for Analysis:

1. Select a portion of the data by using the mouse to position the cursor at one edge of the desired area of the data graph and pressing and holding the left mouse button.
2. Drag the cursor across the desired area. While the cursor is being dragged, the boundaries of the selected

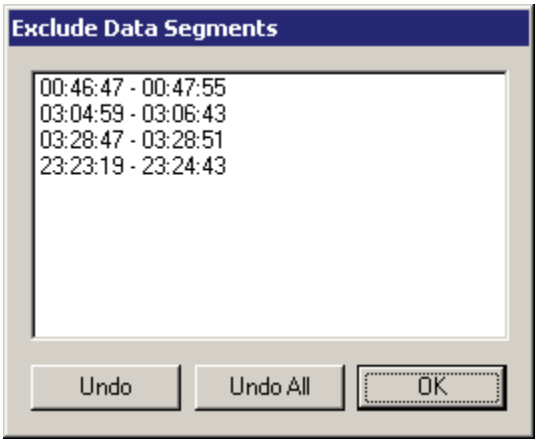
area are marked with a dashed-line rectangle. These boundaries are visible and move as the mouse is moved to show the area selected.

3. When the area of interest is within the rectangle, release the left mouse button. A dashed-line rectangle remains after the left button is released.

Choosing the Summarize Data command from the Edit pull-down menu on the Main Window menu bar or the Summarize icon from the toolbar causes the Summary Statistics dialog box to appear.



When Exclude is selected from the Summary Statistics dialog box, the time interval is added to any existing excluded data segments, and the Excluded Data Segments dialog box appears with the time interval highlighted.



- When Cancel is selected from the Summary Statistics dialog box, the dialog box closes, the dashed-line rectangle disappears from the strip chart, and the data remains in the analysis.

Tip!

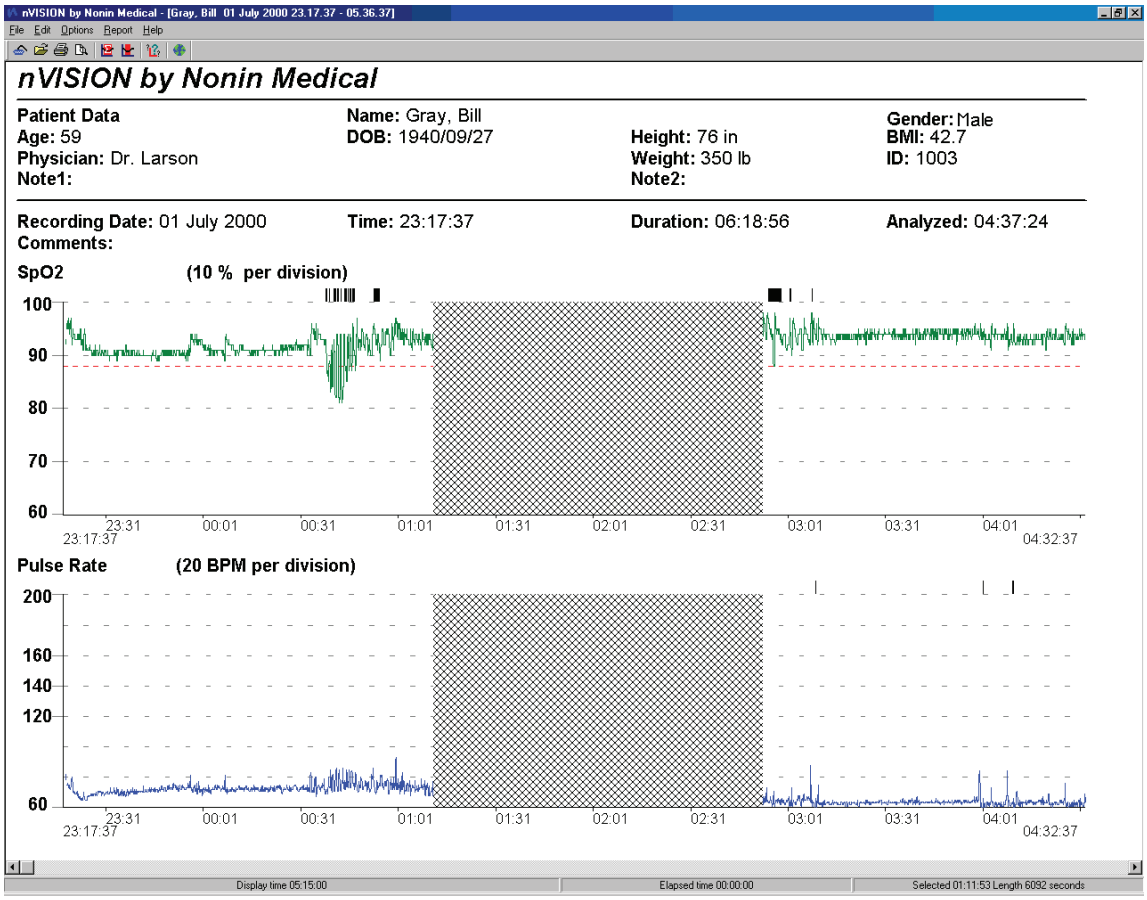
You don't have to use the Summarize Data command. You can go directly to exclude data by clicking on the Exclude Data icon .

See Also:
File Menu Commands

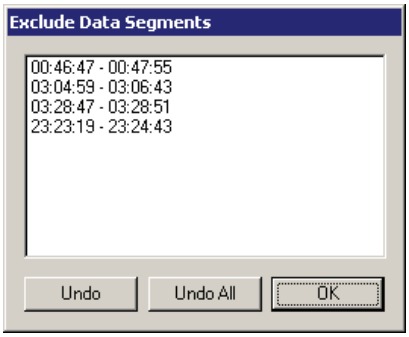
Exclude Data (Edit Menu)

The Exclude Data command, which is under the Edit pull-down menu, is used to exclude selected data segments within a case study from the data analysis.

When you select an area of interest on the Strip Chart Report and then select the Exclude Data command, the Exclude Data dialog box appears with the just-selected data interval excluded. Excluded data will appear as crosshatched patterns when viewed in the Strip Chart or Full Report window or on the printed reports.



When either the Exclude Data command is selected or the Exclude icon on the toolbar is clicked, the Exclude Data Segments dialog box appears:



You can select any single data segment from the Exclude Data Segments list box, using a vertical scroll bar to move up and down the list. The selected data segment appears highlighted.

- When the Undo command is selected, any currently selected data segment is un-excluded from the analysis and the dialog box closes.

- When the Undo All command is selected, all shown data segments are un-excluded from the analysis and the dialog box closes.
- When the OK command is selected, the dialog box is removed, regardless of whether or not a data segment is highlighted. All data segments listed are excluded from the analysis.

NOTE: Manually excluded data are identified in the Strip Chart and Full Study Reports by crosshatched patterns. On the Oximetry Report, excluded data are included in the calculation of % Artifact and in the "Duration" time used to calculate the Index. Excluded data are not used in any other calculations on the Oximetry Report.

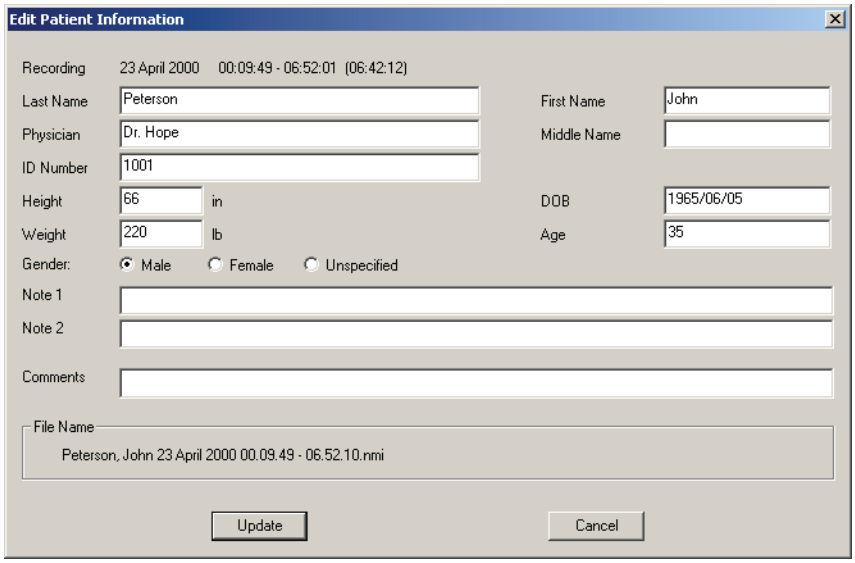
See Also:

File Menu Commands

Patient Info (Edit Menu)

After a saved data set is opened, the Patient Info command is available under the Edit pull-down menu. When the Patient Info command is selected, the Edit Patient Information dialog box appears, allowing users to make case-specific changes to patient information.

NOTE: The data set date/time stamp is automatically inserted at the top of the dialog box.



- When Update is selected, the patient information is updated and automatically saved in the recording, and the dialog box closes.
- When Cancel is selected, any changes made will not be saved, and the dialog box closes.

NOTE: When patient information is updated in the Edit Patient Information dialog box, those updates will only be reflected in the currently open recording. This allows nVISION users to track and record patient changes without changing the patient history file.

Tip

NOTE: Field lengths are limited. The Note 1 and Note 2 fields are limited to 40 characters; the Comments field is limited to 80 characters.

See Also:

File Menu Commands

Patient History File (Edit Menu)

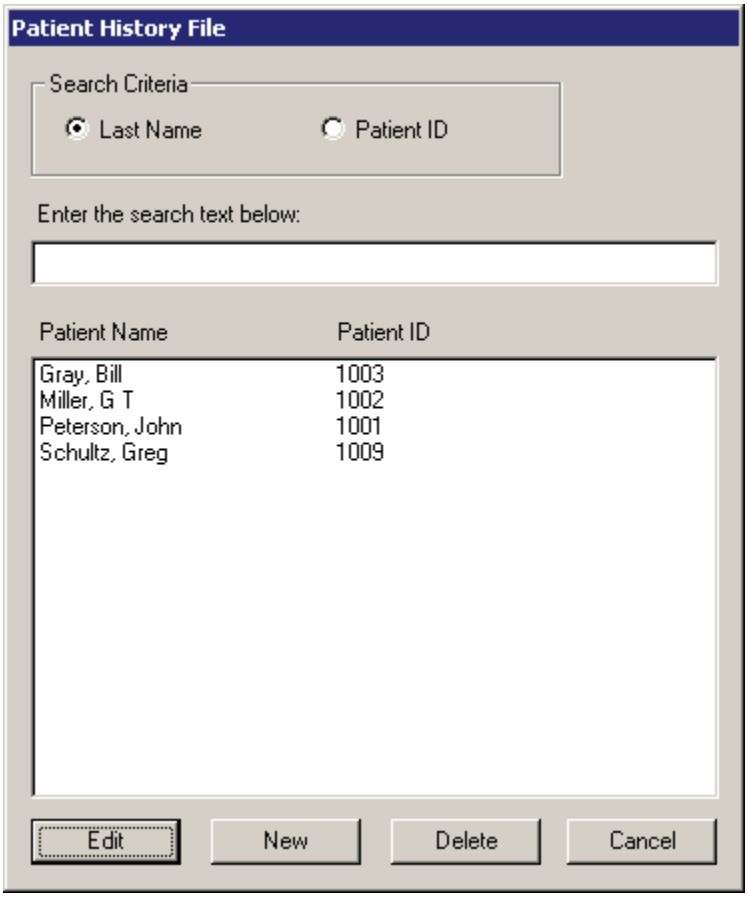
The Patient History File, located under the Edit pull-down menu, serves as a "starting point" for downloading patient data. It is used to store and update entered patient information. The Patient History File recalls the patient information to be associated with a new data file so that the user does not have to re-enter it.

NOTE: Six example case studies are placed in the "DataSets" directory and the Patient History File as part of the initial installation of nVISION.

NOTE: Information in the Patient History File can be updated when no data set is open. When information is updated, those updates are stored in the patient history file, but they are not applied to individual recordings and reports. This allows nVISION users to track and record the patient history without changing the captured recordings. Case-specific information can be saved with individual recordings by making changes in the Edit Patient Information dialog box.

Editing Stored Patient Information

When Patient History File is selected from the Edit pull-down, the Patient History File dialog box appears:

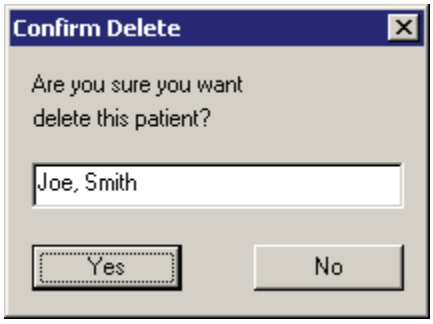


The Patient History File can be sorted by Last Name or Patient ID Number using either the radio buttons in the search criteria section of the dialog box or by typing a the first few letters of a name or ID number in the Search text box. Only one search may be enabled at a time. The Patient Name and Patient ID Numbers for all history file records—sorted by the selected search criteria—are shown in the Patient Name/Patient ID display window.

If you select a patient record and choose Delete, the Confirm Delete dialog box appears with the current patient name displayed. This command allows you to delete patient history information.

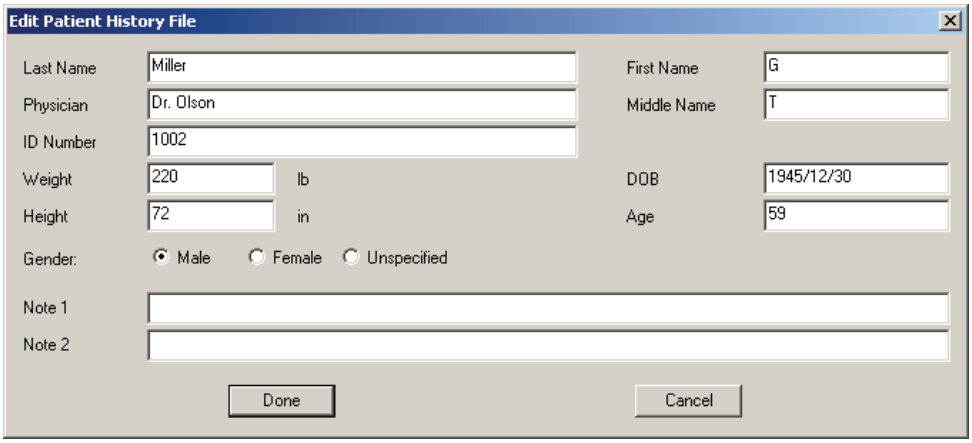
NOTE: You must delete saved case studies (recordings) individually.

- When No is selected, the Confirm Delete dialog box closes and no record is deleted.
- When Yes is selected, the Confirm Delete dialog box closes and the record is deleted.



Use the following procedure to edit patient history files.

1. In the Patient Name/Patient ID display window, click on the data segment you wish to edit.
2. Click the Edit button at the bottom of the dialog box. The Edit Patient History File dialog box appears, with current patient information displayed.



NOTE: When information is updated in the Edit Patient History File dialog box, those updates are stored in the patient history file, but they are not applied to individual recordings. Case-specific information can be saved with individual recordings by making changes in the Edit Patient Information dialog box. Changes made in the Edit Patient Information dialog box do not affect the Patient History File; they only apply to the currently open recording.

3. Click in each box to edit patient information, or use your computer's Tab key to navigate to each box.

- When Done is selected, the patient information is updated and the dialog box closes.
- When Cancel is selected, the dialog box closes and no changes are saved.

Tip

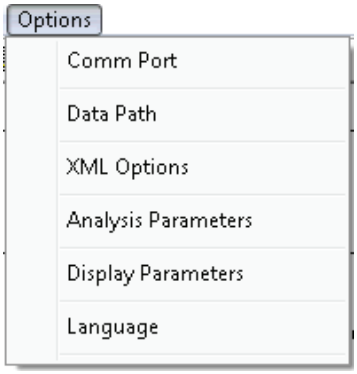
NOTE: If you need to delete all text in one of the boxes, enter one space (press the Space bar one time) before clicking the Done button.

See Also:

File Menu Commands

Options Menu Commands

The commands in the Options menu allow the user to configure several nVISION parameters. The selected configuration options are saved by nVISION. If no settings are changed by the user, nVISION will use the default configuration.

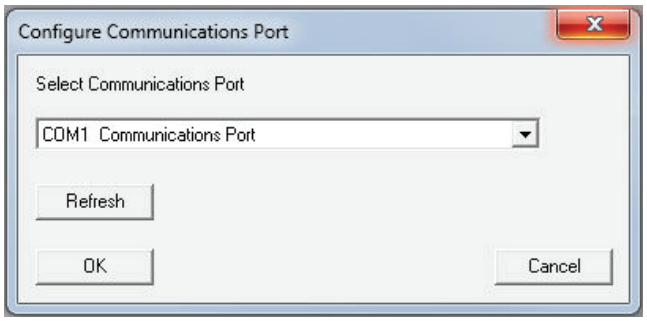


The following commands appear under the Options menu. Click on a command for more information.

- Comm Port
- Data Path
- XML Options
- Analysis Parameters
- Display Parameters
- Language

Comm Port (Options Menu)

When the Comm Port (communications port) command under the Options menu is selected, the Configure Communications Port dialog box appears:



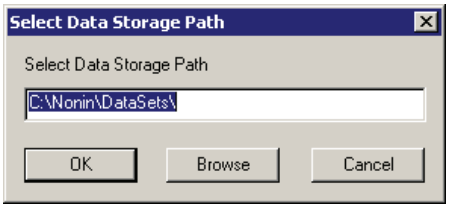
- When OK is selected, the currently selected communications port will be used for data capture and the dialog box closes.
- When Cancel is selected, any changes to the communications port are lost and the dialog box closes.

If a Bluetooth wireless connection is being used, the Comm port associated with that device when it was paired must be selected. Refer to the instructions for the Bluetooth stack being used to determine how to do this.

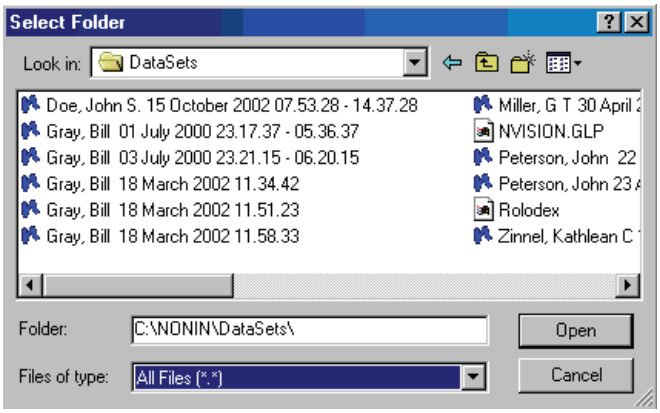
See Also:
Options Menu Commands

Data Path (Options Menu)

When the Data Path command under the Options menu is selected, the Select Data Storage Path dialog box appears:



- When OK is selected, the currently selected path is used for the default data capture path and the dialog box closes. Data sets (case studies) are stored to the currently selected location.
- When Cancel is selected, any changes to the default data storage path is lost and the dialog box closes.
- When Browse is selected, the Select Folder dialog box appears, allowing the user to browse the directory structure:



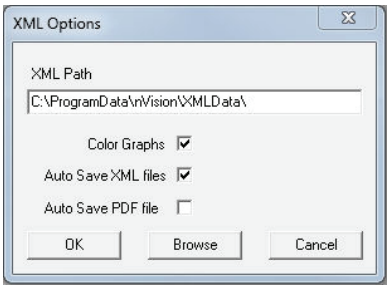
- When Cancel is selected, the Select Folder dialog box closes.
- When Open is selected, the Select Folder dialog box closes and the Select Data Storage Path dialog box appears, with the current folder from the Select Folder dialog box selected.

See Also:

Options Menu Commands

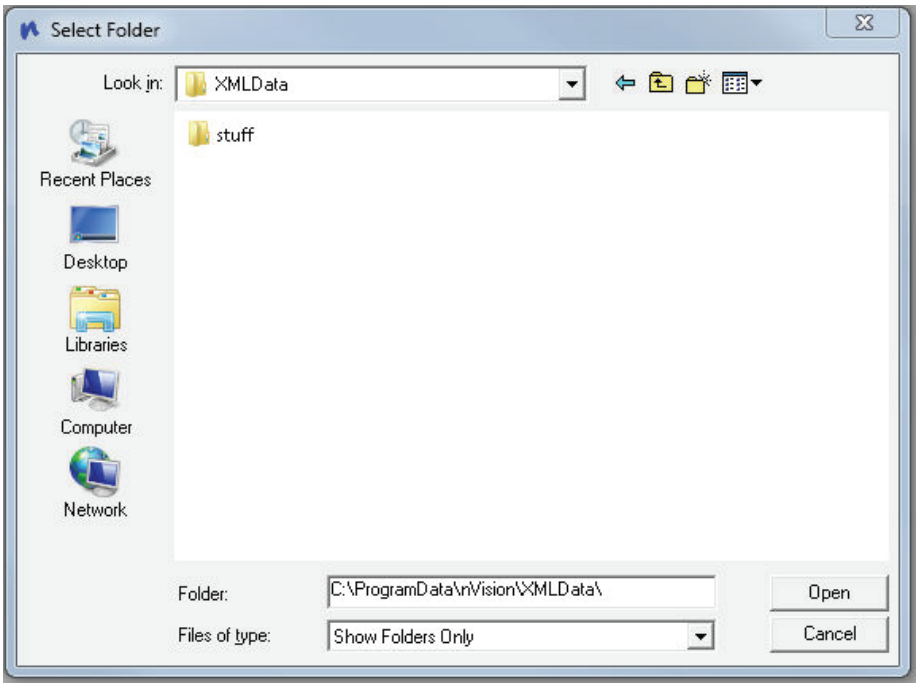
XML Options

When the XML Options command under the Options menu is selected, the XML Options dialog box appears:



- When Color Graphs is selected, the graph lines in the XML graph files will be the same color as on the screen. Otherwise they will be black.
- When Auto Save XML files is selected, the XML files will be saved at the same time as the study when it is downloaded from the oximeter and selected from the list.
- When Auto Save PDF file is selected, the PDF file will be generated and saved when the study is first downloaded.
- When OK is selected, the currently selected path is used for the default data capture path and the dialog box closes. Data sets (case studies) are stored to the currently selected location.
- When Cancel is selected, any changes to the default data storage path is lost and the dialog box closes.

- When Browse is selected, the Select Folder dialog box appears, allowing the user to browse the directory structure:



Analysis Parameters (Options Menu)

The Analysis Parameters command is under the Options pull-down menu. When the Analysis Parameters command is selected, the following data analysis parameters can be changed:

SpO2 Parameters

- Percent Drop for Event (%): value, in %, to qualify as an SpO2 (Desaturation) Event.
- Minimum Event Duration (sec): value, in seconds, of SpO2 decrease that qualifies as an SpO2 (desaturation) event.
- Desaturation Criteria Level (%): value, in %, below which the SpO2 level must drop to be classified in a special category of statistics. This threshold is indicated on the SpO2 graph by a red guide line.

Pulse Rate Parameters

- Rate Change For Event (bpm): value, in beats per minute, to qualify as a Pulse Rate Event.
- Minimum Event Duration (sec): value, in seconds, of Pulse Rate Change to qualify as a pulse rate event.

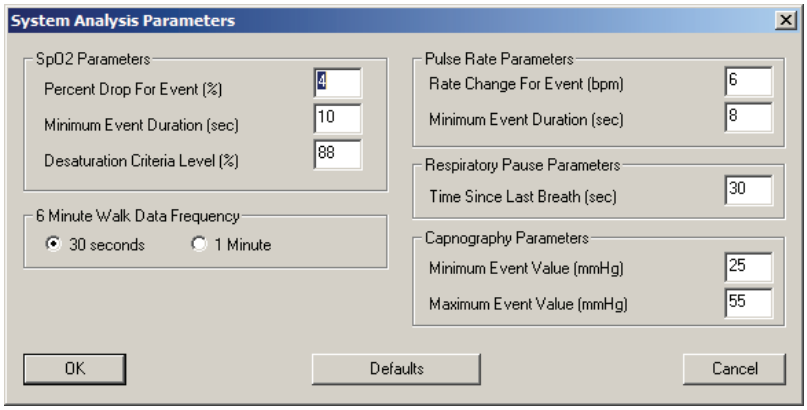
Respiratory Rate Parameters

- Time Since Last Breath (sec): value, in seconds, since last breath to qualify as a Respiratory Pause Event.

6 Minute Walk Data Frequency

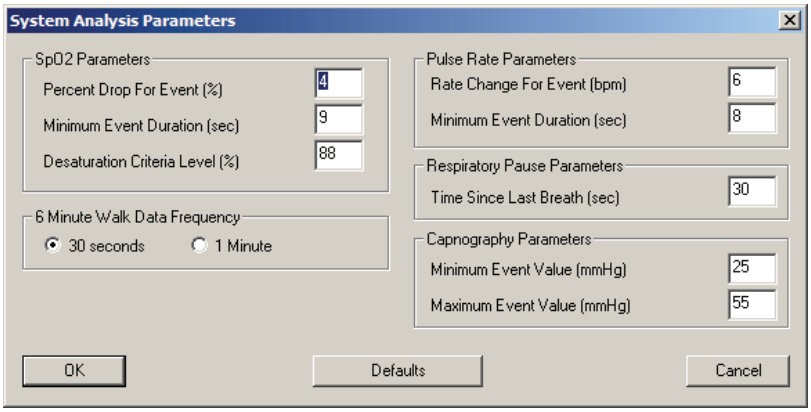
- Controls whether the 6 minute walk report shows data in 30 second or 1 minute intervals.

System Analysis Parameters



System default parameters can be changed to reflect your protocol. They will be applied to any new downloaded data set when initially opened.

With no data set open, select the Analysis Parameters command. The System Analysis Parameters dialog box opens. The values shown on screen may be set to factory defaults (shown above) or may reflect changes set by a user like the box shown below:



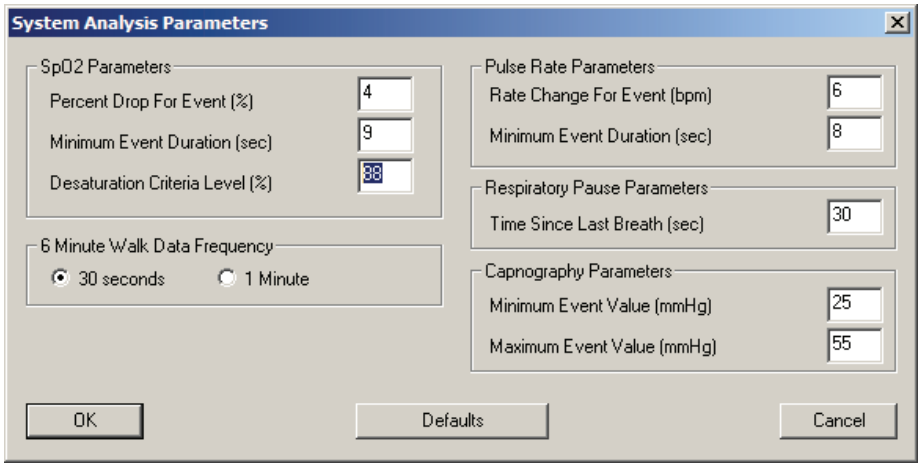
Click in any box to change a value, or use the computer's Tab key to navigate between boxes.

- When OK is selected, any changes made to the analysis parameters are saved and the dialog box closes.
- When Defaults is selected, all parameters are reset to the factory default settings.
- When Cancel is selected, any changes to the analysis parameters are lost and the dialog box closes.

NOTE: The System Analysis Parameters are saved with the case when data are downloaded from the pulse oximeter and saved as a data set.

Case Specific Analysis Parameters

To change the Analysis Parameters on a per case basis, open the pertinent data set. Select the Analysis Parameters command from the Options pull-down menu. The Case Specific Analysis Parameters dialog box appears:



The values shown on screen may be set to System parameters by clicking the Defaults button or may reflect changes set by a user and saved with the case.

Click in any box to change a value or use the computer's Tab key to navigate between boxes.

- When OK is selected, any changes made to the analysis parameters are saved for use by this case only and the dialog box closes. If you wish to save these parameters as a separate data set, select the Save As command from the File pull-down menu and save the data set with a new file name. Otherwise, the Save command can be used to store the new analysis parameters with the data set.
- When Defaults is selected, all parameters are reset to the System Analysis Parameters in effect at that time.
- When Cancel is selected, any changes to the analysis parameters are lost and the dialog box closes.

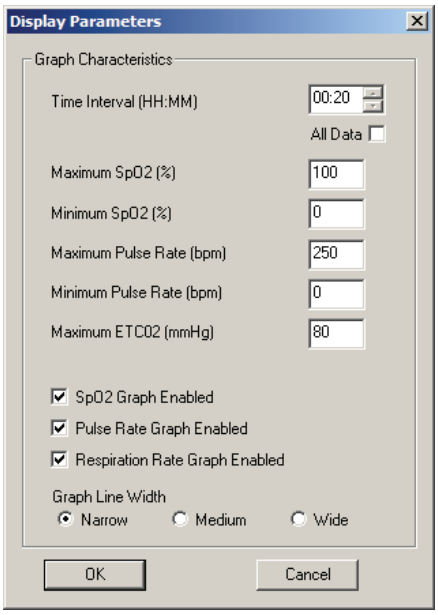
See Also:

Options Menu Commands
Display Parameters
Editing Data
Analyzing Data

Display Parameters (Options Menu)

Display parameters are items that are set up or modified to obtain desired report outputs. Selecting the Display Parameters command from the Options pull-down menu brings up a dialog box that allows you to adjust the scales for viewing data. Through this dialog box, you can select how much time on the x-axis will fit in the window and adjust the range of values for pulse rate, saturation, or respiration rate on the y-axis.

After selecting the Display Parameters command or clicking the Display Parameters icon on the toolbar, the Display Parameters dialog box appears:



The display parameter choices are as follows:

- If All Data is not checked, the amount of data indicated by Time Interval will be displayed on a single screen or on one printed page of the Full Study Report or Strip Chart Report.
- When All Data is checked, the x-axis is automatically adjusted so that all data fits on the screen at one time when viewed with the Strip Chart Report or printed with the Full Study Report. (In some cases, up to 5 minutes of data may be off screen.)
- Maximum SpO2(%): The upper limit on the y-axis of the SpO2 graph.
- Minimum SpO2(%): The lower limit on the y-axis of the SpO2 graph.
- Maximum Pulse Rate (bpm): The upper limit on the y-axis for the pulse rate graph.
- Minimum Pulse Rate (bpm): The lower limit on the y-axis for the pulse rate graph.

The Display Parameters dialog box also contains check boxes to enable or disable the SpO2 graph, Pulse Rate graph, and Respiration Rate graph on the Strip Chart Report.

The line width selection determines the width of the line used in graphs. Narrow provides the most data resolution. The other values are typically only useful when faxing reports.

- When OK is selected, any changes to the display parameters are saved and the dialog box closes.
- When Cancel is selected, any changes to the display parameters are lost and the dialog box closes.

See Also:

Options Menu Commands

Language (Options Menu)

The Language command, which is located under the Options pull-down menu, allows you to switch between several languages for generating and printing reports.

After selecting the Language command or clicking the Language icon on the toolbar, the Language dialog box appears:

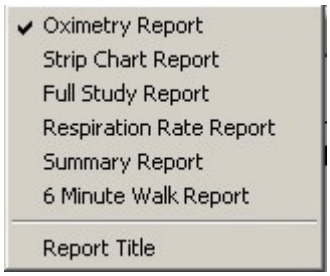
See Also:

Options Menu Commands

Report Menu Commands

The commands in the Report menu allow you to select the type of report (Oximetry, Strip Chart, Full Study, Respiration Rate, or Summary Report) you'd like to generate, view, or print. The Report Title command allows you to set the report title.

Click on a command below for more information.



- Oximetry Report
- Strip Chart Report
- Full Study Report
- Respiration Rate Report
- Summary Report
- 6 Minute Walk Report

Only one of the report types may be selected at a time. The currently selected report type will be indicated in the Report menu with a check mark to the left of the report type. The default report type is Strip Chart when a data set is first opened.

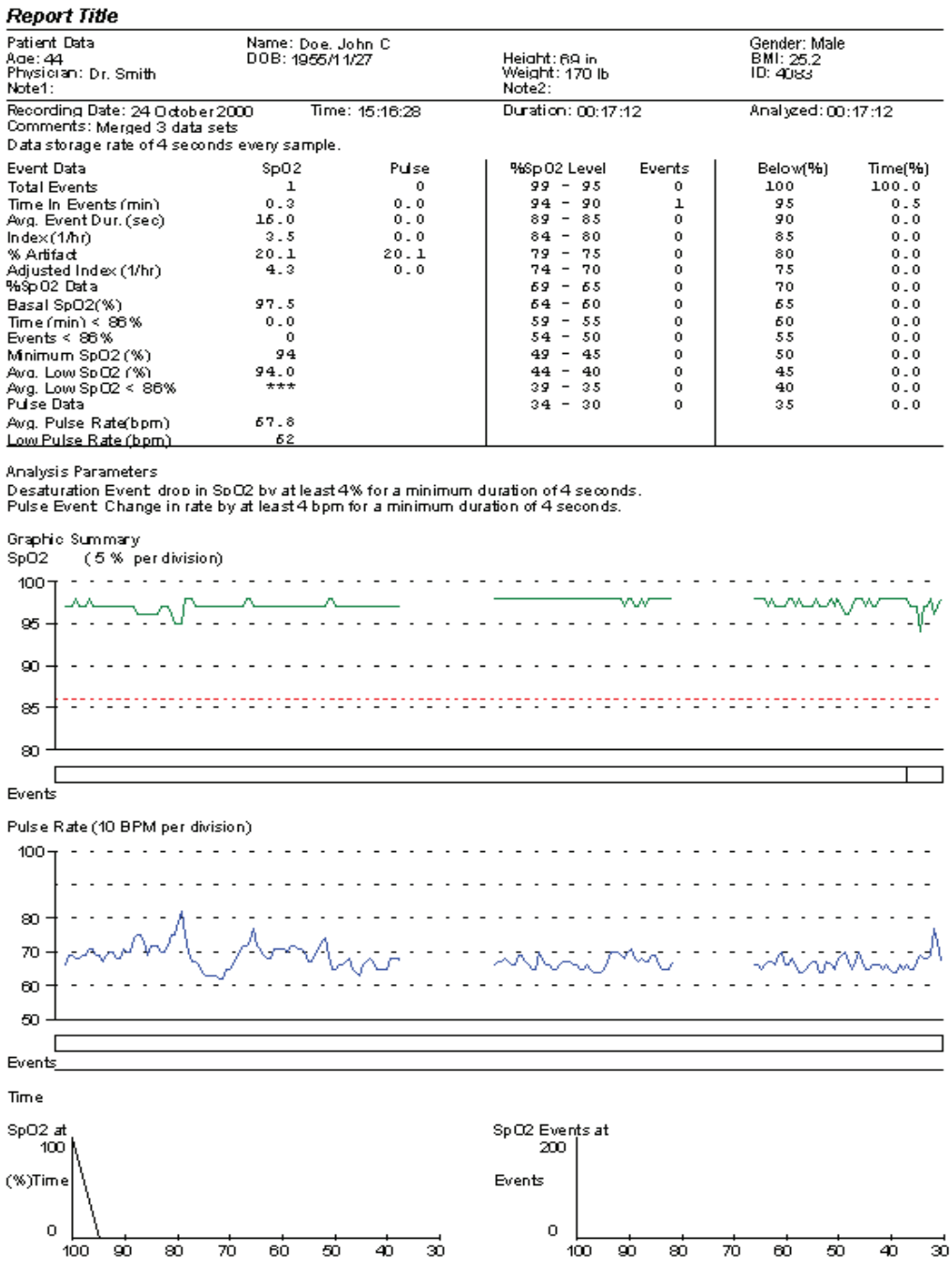
See Also:

Report Descriptions
Printing Reports

Oximetry Report (Report Menu)

The Oximetry Report command is under the Report menu. When the Oximetry Report command is selected, the following report appears on screen for the currently open data set.

NOTE: The Oximetry Report is one page in length.



Report Title

Patient Data
Age: 44
Physician: Dr. Smith
Note1:

Name: Doe, John C
DOB: 1955/11/27

Height: 69 in
Weight: 170 lb
Note2:

Gender: Male
BMI: 25.2
ID: 4083

Recording Date: 24 October 2000 Time: 15:16:28 Duration: 00:17:12 Analyzed: 00:17:12
Comments: Merged 3 data sets
Data storage rate of 4 seconds every sample.

Event Data	SpO2	Pulse
Total Events	1	0
Time In Events (min)	0.3	0.0
Avg. Event Dur. (sec)	16.0	0.0
Index (1/hr)	3.5	0.0
% Artifact	20.1	20.1
Adjusted Index (1/hr)	4.3	0.0
%SpO2 Data		
Basal SpO2(%)	97.5	
Time (min) < 86%	0.0	
Events < 86%	0	
Minimum SpO2 (%)	94	
Avg. Low SpO2 (%)	94.0	
Avg. Low SpO2 < 86%	***	
Pulse Data		
Avg. Pulse Rate(bpm)	67.8	
Low Pulse Rate (bpm)	62	

%SpO2 Level	Events	Below(%)	Time(%)
99 - 95	0	100	100.0
94 - 90	1	95	0.5
89 - 85	0	90	0.0
84 - 80	0	85	0.0
79 - 75	0	80	0.0
74 - 70	0	75	0.0
69 - 65	0	70	0.0
64 - 60	0	65	0.0
59 - 55	0	60	0.0
54 - 50	0	55	0.0
49 - 45	0	50	0.0
44 - 40	0	45	0.0
39 - 35	0	40	0.0
34 - 30	0	35	0.0

Analysis Parameters
Desaturation Event: drop in SpO2 by at least 4% for a minimum duration of 4 seconds.
Pulse Event: Change in rate by at least 4 bpm for a minimum duration of 4 seconds.

Graphic Summary
SpO2 (5 % per division)
100
95
90
85
80
Events

Pulse Rate (10 BPM per division)
100
80
70
60
50
Events

Time

SpO2 at
100
(%)Time
0
100 90 80 70 60 50 40 30

SpO2 Events at
200
Events
0
100 90 80 70 60 50 40 30

- The vertical scroll bar can be used to examine the report data.
- When the Print Preview command is selected, the report is shown as it would appear when printed.
- When the Print command is selected, the report is printed.

The Oximetry Report is a one-page summary of a case study that focuses primarily on event data as defined by the analysis parameters. Excluded data are subtracted from the total study time (duration) to indicate the time analyzed.

The key sleep study statistic is called the "index," which is calculated as events per hour. Summary statistics for events will be total number of events, cumulative time spent in events, average event duration, raw index value, and the adjusted index where artifact and excluded data are not used. The duration of the record and total time interval analyzed will be reported.

The basal SpO2 is calculated as an average of steady-state readings (average of SpO2 readings during non-event times). A further analysis of SpO2 values divides the record into 2 types of data representation, based on the Desaturation Criteria Level set in the Analysis Parameters dialog box.

The cumulative time spent below the Desaturation Criteria Level is reported. The total number of events that occurred below the Desaturation Criteria Level is reported. The minimum SpO2 value is reported. An average low SpO2 value and an average low SpO2 value below the "Desaturation Criteria Level" is reported.

De-Sat Event Reporting

nVISION uses a drop of 6% and an event duration of 8 seconds as the default desaturation event criteria. The Analysis Parameters command on the Options pull-down menu allows the user to select a different percentage change as the desaturation criteria or a different value for the amount of time over which the drop in saturation must occur. A summary in the Oximetry Report shows the number of events occurring in each 5-percentage point interval from 30% to 100% and the cumulative percent of time spent below each interval level.

Pulse Rate Event Reporting

nVISION uses a pulse rate change of 6 bpm and an event duration of 8 seconds as the default pulse rate event criteria. The Analysis Parameters command on the Options pull-down menu allows you to select a different pulse rate change or a different value for the amount of time over which the change in pulse rate must occur in order to be considered an event. A Pulse Data summary section in the Oximetry Report shows the average pulse rate in bpm and the minimum pulse rate seen.

Mark Events on Data Graphs

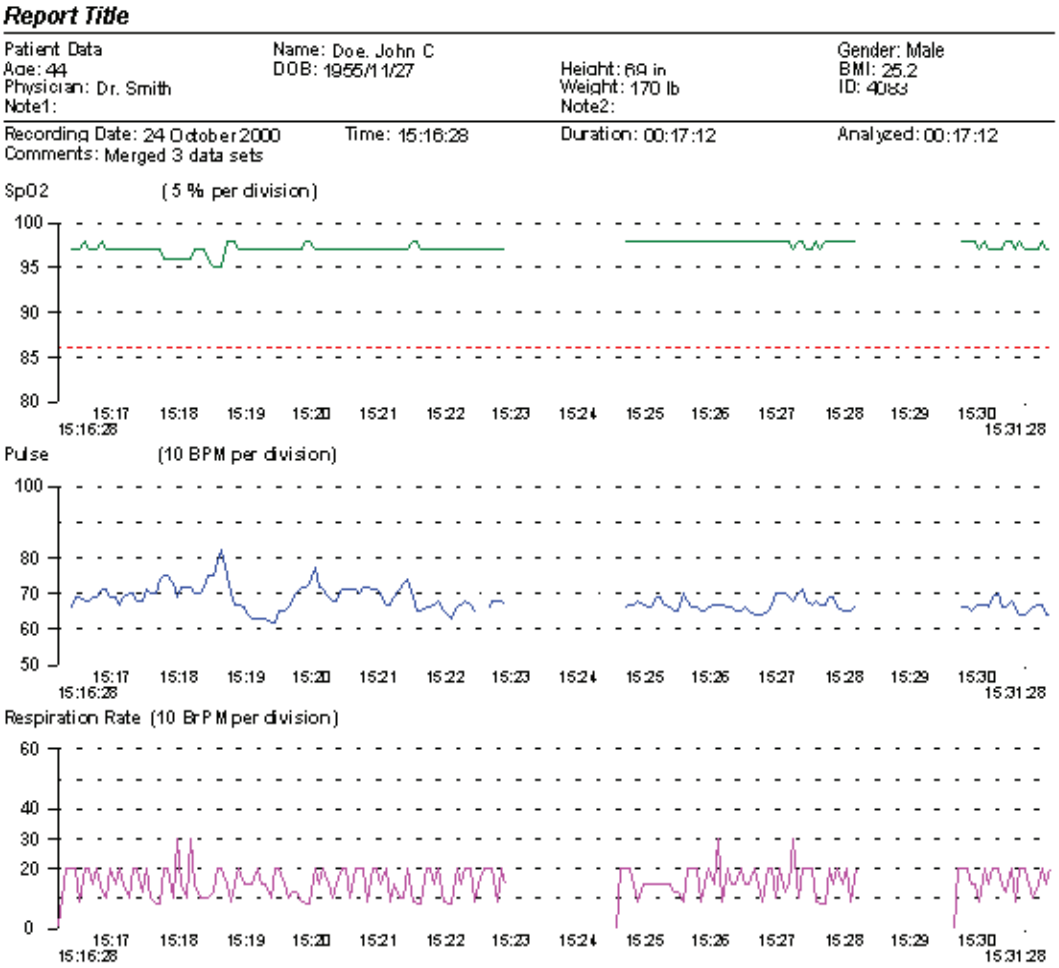
An "Event Bar" is located below the Graphic Summary strip chart in the Oximetry Report to show where events occurred when the analysis parameters were applied. Events for each type of parameter are evaluated separately and located under the respective graph.

See Also:

Report Menu Commands
Print Preview
Printing Reports

Strip Chart Report (Report Menu)

The Strip Chart Report command is under the Report menu. When the Strip Chart Report command is selected, the following report appears on screen for the currently open data set:



NOTE: This report may be more than one page long, depending upon the duration of the recording and the time interval selected in the Display Parameters dialog box.

The Strip Chart Report allows the user to view raw data on the screen as a visual strip chart recording. The purpose of the Strip Chart report is to allow the user to evaluate the data and perform the necessary analysis to exclude noisy or suspect data and to select the scales for printing the Full Study Report. A scroll bar along the bottom of the data display window, as well as Page Up and Page Down keys on the keyboard, allow the user to move through the data. The timelines are synchronized between stacked windows.

Artifact data are seen as a gap in the graph, rather than going to zero; so as not to be interpreted as an event.

The X-axis and Y-axis scales are adjustable by selecting the Display Parameters command in the Options pull-down menu.

The user can select a portion of the data over which to calculate summary statistics. For more information on obtaining summary statistics for selected data within a data set, see Summarize Data.

When the cursor is placed over a point in a graph, right-clicking the mouse displays the data values at that time in the right side of the status bar.

nVISION provides an additional strip chart for respiration rate with the Nonin 9840 series and TrendSense devices.

Event bars are marked according to analysis parameter criteria and are located above the corresponding data.

When the Strip Chart Report is active, the Print icon on the toolbar allows the user to print what is currently shown in the window.

A status bar, located at the bottom of the screen, shows the Display Time Interval and the Elapsed time since the start of the data set.

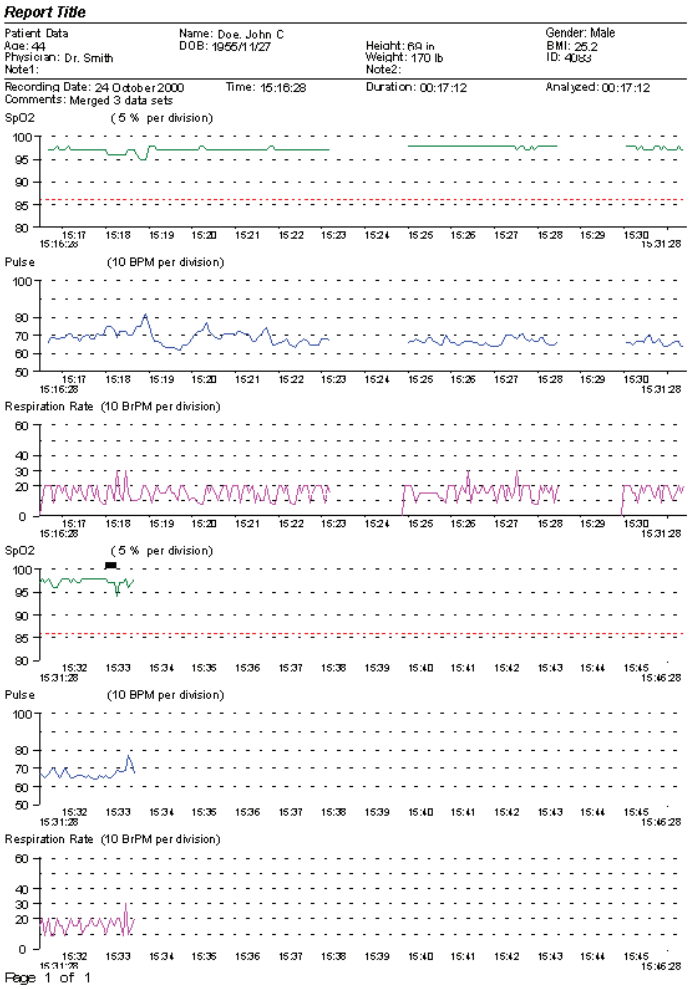
- When the Print Preview command is selected, the screen is shown as it would appear when printed.
- When the Print command is selected, the screen is printed.

See Also:

Report Menu Commands
Print Preview
Printing Reports

Full Study Report (Report Menu)

The Full Study Report command is under the Report menu. When the Full Study Report command is selected, the following report appears on screen for the currently open data set:



The Full Study Report includes all the data, represented in graphical format, arranged on as many pages as it

take to print that data to the scale selected by the settings from the Display Parameters dialog. Crosshatched patterns are drawn on the graphs to show the segments excluded from analysis.

NOTE: This report may be more than one page long, depending upon the duration of the recording and the time interval selected in the Display Parameters dialog box.

Events, which are calculated using the default or user-defined event criteria, are indicated by black bars above the data in the Full Study Report.

- When Print Preview is selected, the report is shown as it would appear when printed.
- When Print is selected, the report is printed.

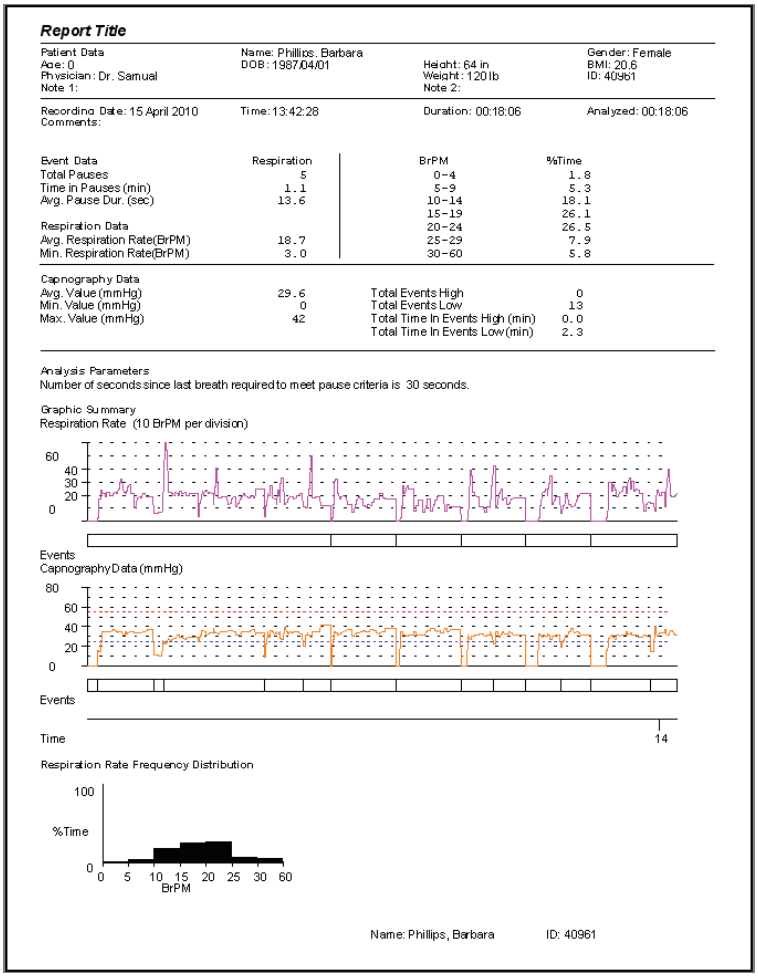
See Also:

Report Menu Commands
Print Preview
Capnography

Capnography

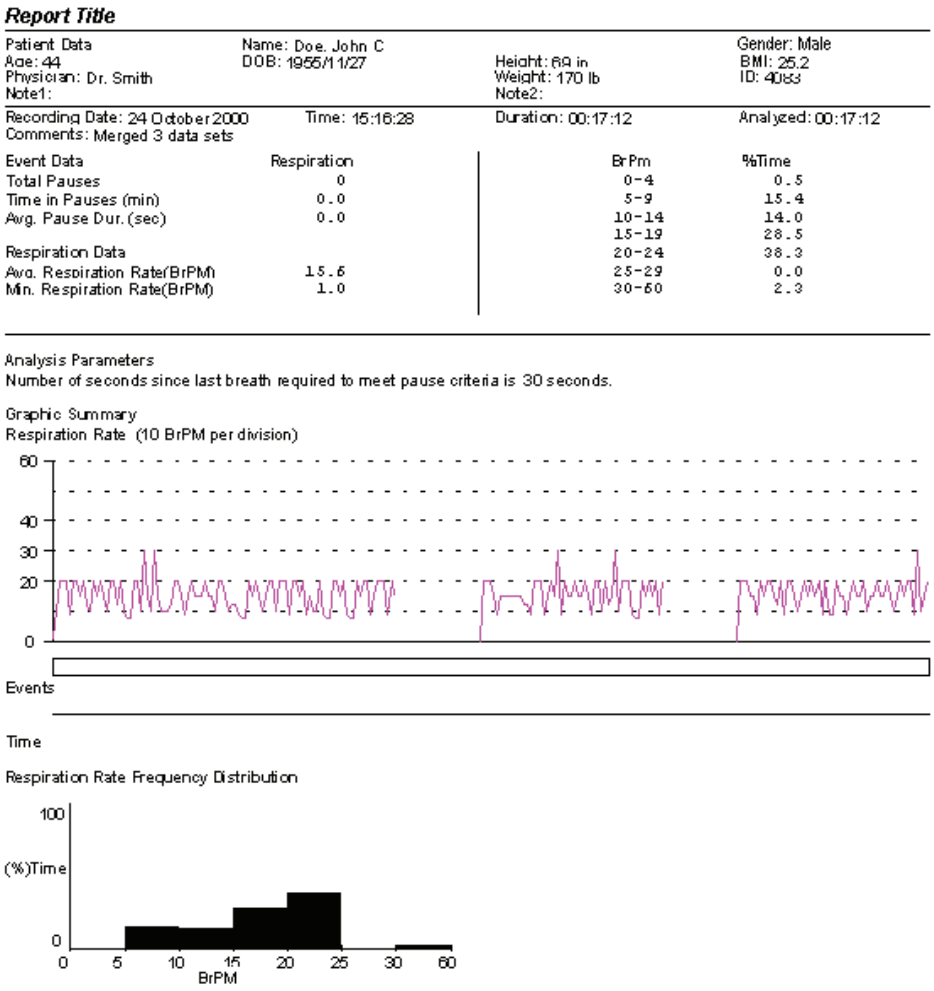
nVision will supply capnography data on a second graph of the respiration report if such data is available from the TrendSense module. Two parameters are available under Analysis Parameters to set the high and low event lines. Another parameter is available under Display Parameters to set the maximum value for the Y-axis of the capnography graph. All values displayed are in mmHg (millimeters of mercury).

Note: All capnography data will be displayed in mmHG. Data collected in kPa (Kilopascals) will be converted to mmHG during the download.



Respiration Rate Report (Report Menu)

The Respiration Rate Report command is available under the Report menu when respiration data has been recorded (using the Nonin Model 9840 or TrendSense series). When the Respiration Rate Report command is selected, the following report appears on screen for the currently open data set:



The Analysis Parameters command on the Options pull-down menu allows the user to select a respiratory pause criteria to calculate summary respiratory data. Summary statistics are the total number of pauses, cumulative time spent in pauses, average pause duration, minimum respiration rate, and average respiration rate where artifact and excluded data are not included.

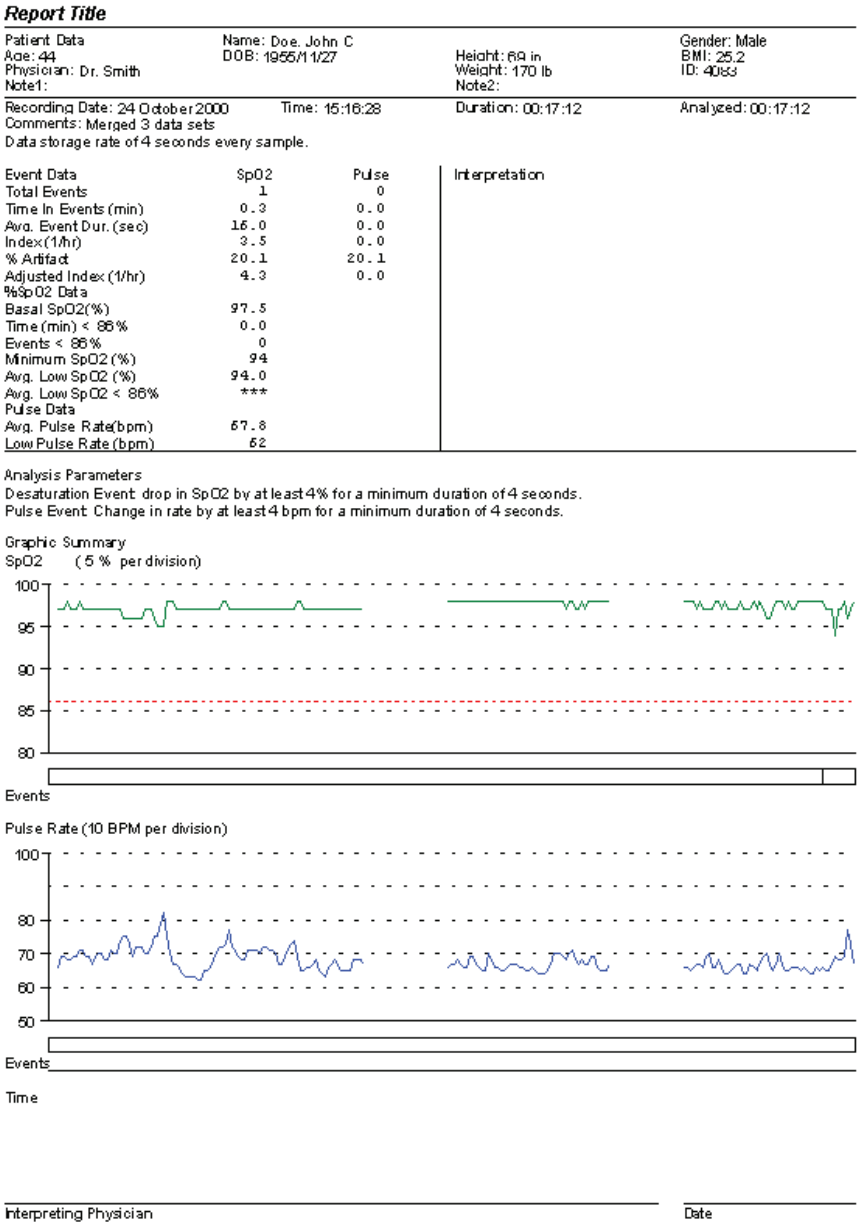
- When Print Preview is selected, the report is shown as it would appear when printed.
- When Print is selected, the report is printed.

See Also:

Report Menu Commands
Print Preview
Printing Reports
Capnography

Summary Report (Report Menu)

The Summary Report can be selected from the Report menu. When Summary Report is selected, the following report appears on screen for the currently open data set:



Report Title

Patient Data
Age: 44
Physician: Dr. Smith
Note1:

Name: Doe, John C
DOB: 1955/11/27

Height: 69 in
Weight: 170 lb
Note2:

Gender: Male
BMI: 25.2
ID: 4083

Recording Date: 24 October 2000 Time: 15:16:28 Duration: 00:17:12 Analyzed: 00:17:12
Comments: Merged 3 data sets
Data storage rate of 4 seconds every sample.

Event Data	SpO2	Pulse	Interpretation
Total Events	1	0	
Time In Events (min)	0.3	0.0	
Avg. Event Dur. (sec)	16.0	0.0	
Index (1/hr)	3.5	0.0	
% Artifact	20.1	20.1	
Adjusted Index (1/hr)	4.3	0.0	
%SpO2 Data			
Basal SpO2(%)	97.5		
Time (min) < 86%	0.0		
Events < 86%	0		
Minimum SpO2 (%)	94		
Avg. Low SpO2 (%)	94.0		
Avg. Low SpO2 < 86%	***		
Pulse Data			
Avg. Pulse Rate(bpm)	67.8		
Low Pulse Rate (bpm)	62		

Analysis Parameters
Desaturation Event: drop in SpO2 by at least 4% for a minimum duration of 4 seconds.
Pulse Event: Change in rate by at least 4 bpm for a minimum duration of 4 seconds.

Graphic Summary
SpO2 (5 % per division)
100
95
90
85
80
Events
Pulse Rate (10 BPM per division)
100
80
70
60
50
Events
Time

Interpreting Physician Date

The Summary Report provides a good overview—using case-specific analysis parameters—of the patient during the monitoring period. The report is divided into four sections:

- Patient Data
- Numerical Data Summary, with detailed event data, %SpO2 data, and pulse rate data
- Analysis parameters (parameters used to analyze patient data)
- Graphic summary

The Summary Report includes a number of graphic summaries:

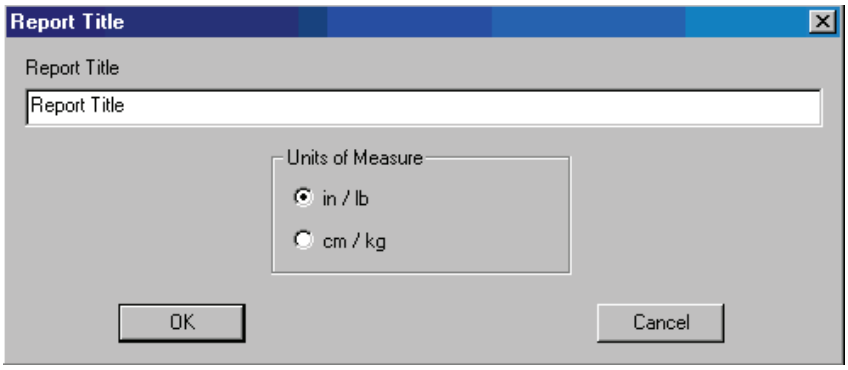
- First is a graphical representation of the patient's SpO2 data.
- Directly under this graph is a summary of detected SpO2 events (identified by vertical bars).
- Next is a graphical representation of the patient's pulse rate data.
- Directly under this graph is a summary of detected pulse events (identified by vertical bars).
- Time is indicated under the last graphic summary (in this case, the Pulse Rate graph). Time is marked to the nearest hour.

In addition, the Summary Report includes an Interpretation Area (for reviewer comments) and a Physician Signature Block (for insurance and record-keeping purposes). Data can be entered in the Interpretation Area by double clicking within the blank space. This opens a new window for data entry.

NOTE: See Oximetry Report for information about De-Sat Event Reporting, Pulse Rate Event Reporting, and Marking Events on Data Graphs.

Report Title (Report Menu)

The Report Title command is under the Report menu. When the Report Title command is selected, the following dialog box appears:



NOTE: Before capturing (downloading) new data for the first time, choose the Report Title command from the Report pull-down menu The Report Title dialog box appears. Enter the report title (usually a facility name). The dialog box also contains the Units of Measure radio button for inches/pounds (in/lb) or centimeters/kilograms (cm/kg). Select the desired English or metric units. These settings remain in nVISION until you change them. Often these settings will be changed only once, at the time of the initial setup.

Report Title and Units of Measurement

The Report pull-down menu includes a command that allows the user to customize the title that appears on printed reports. This same dialog box allows the user to select English or Metric units used for patient information.

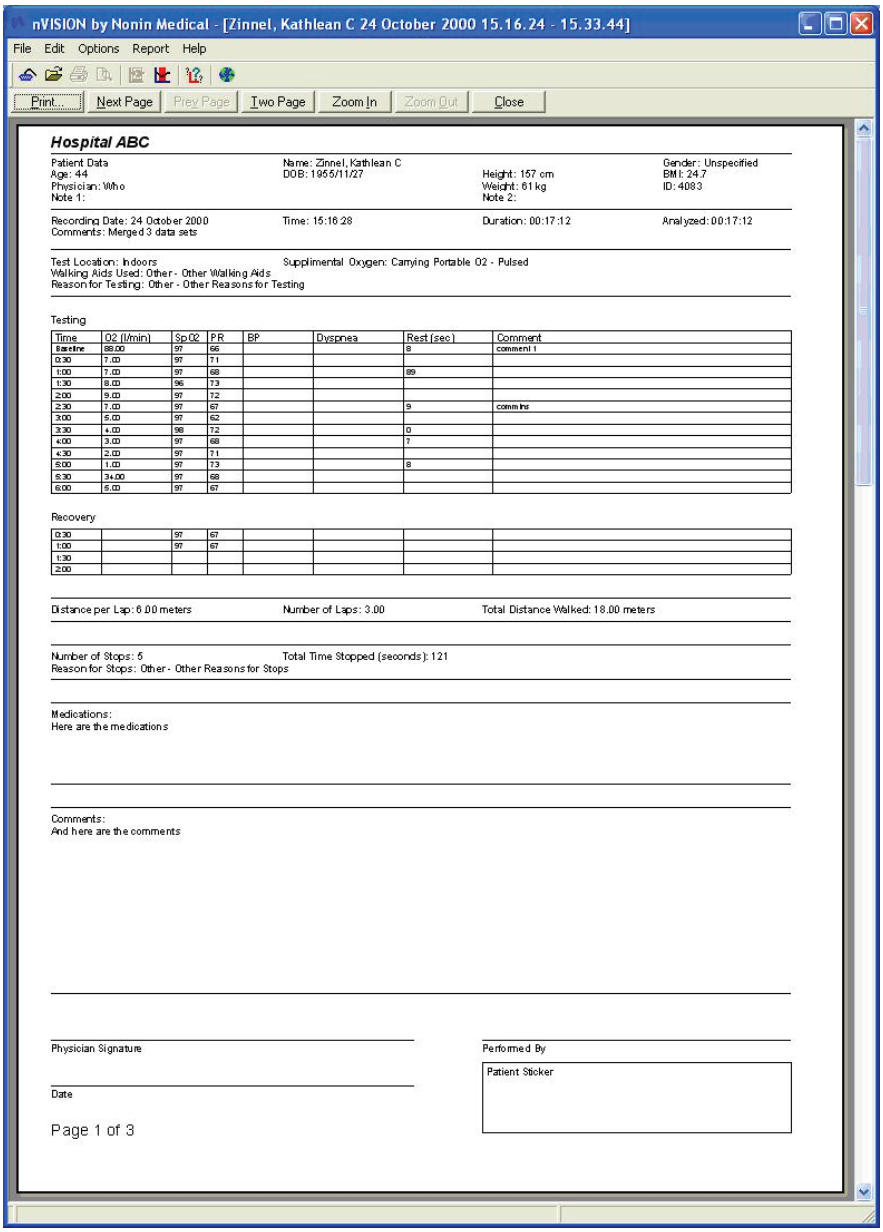
- When OK is selected, any changes to the report title and units of measure made are saved and the dialog box closes.
- When Cancel is selected, any changes to the report title and units of measure are lost and the dialog box closes.

See Also:

Report Menu Commands
Print Preview
Printing Reports

6 Minute Walk Report (Report Menu)

The 6 Minute Walk Report can be selected from the Report menu. When this report is selected, the following report appears on the screen.



Double clicking anywhere on the screen brings up a data input window that allows the user to enter data for all the fields that are not filled in by the oximetry data. All data is automatically saved when the window is closed.

Printing the 6 Minute Walk Report will cause both the first page and any additional pages containing the oximetry data to be printed. Only the first page can be displayed by nVISION.

Help Menu Commands

The following commands appear under the Help pull-down menu.

Help Topics

Use the Help Topics to learn more about nVISION software.

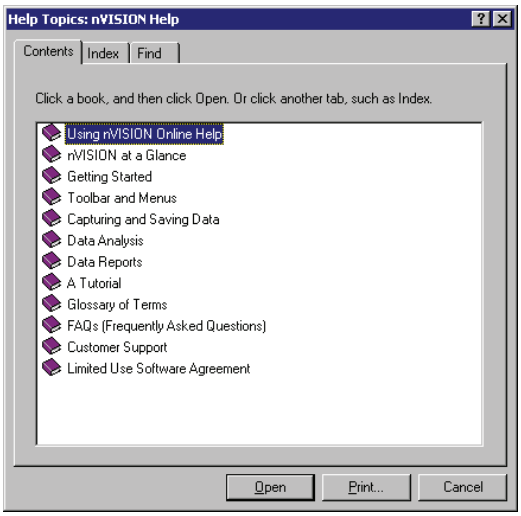
- Choose the Contents tab to review the Help table of contents
- Choose the Index tab to review the Help index entries
- Choose the Find tab to search for a specific word or words in the Help topics.

About nVISION

The About nVISION window displays information about nVISION software, including version number, key code number, and registration information.

Help Topics (Help Menu)

The Help Topics command is under the Help menu. When the Help Topics command is selected, a dialog box with Contents, Index, and Find tabs appears.



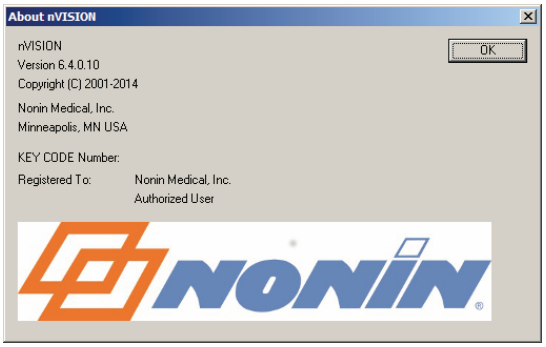
See Also:

Getting Help With nVISION

About nVISION (Help Menu)

When the About nVISION command under the Help menu is selected, the About nVISION dialog box appears.

Each version of nVISION displays a unique key code in the About nVISION dialog box. This key code is necessary for installing nVISION software and for obtaining customer support for the software.



This window displays the nVISION software Version Number and the key code entered when installing nVISION software.

See Also:

Help Menu Commands

Capturing and Saving Data

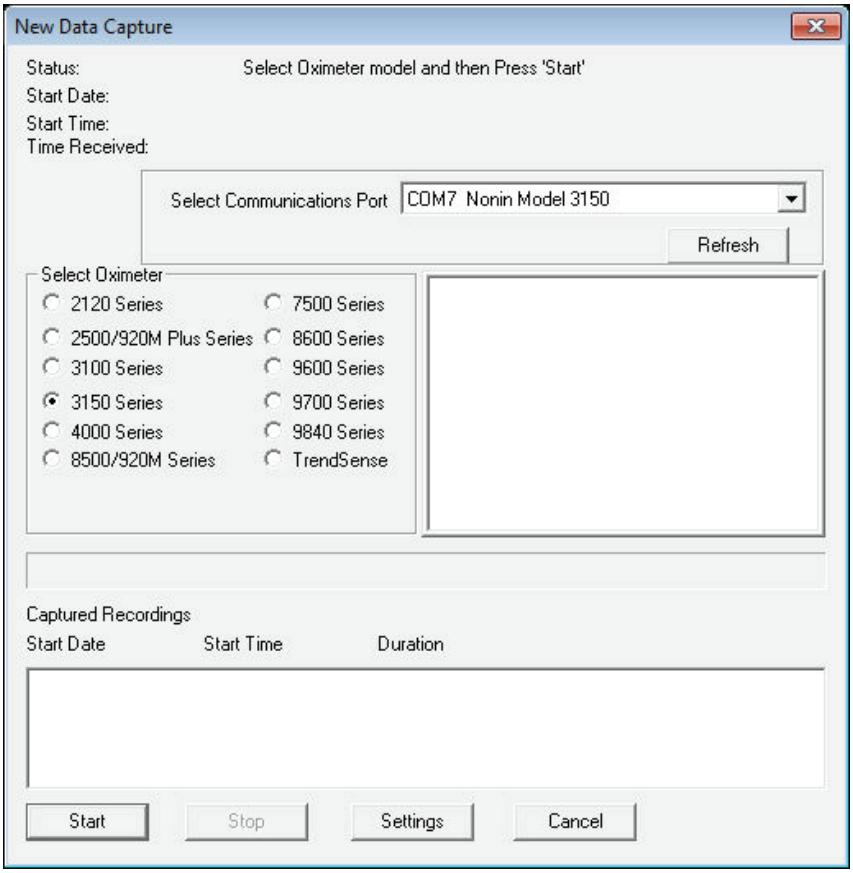
NOTE: Before capturing (downloading) new data for the first time, choose the Report Title command from the Report pull-down menu The Report Title dialog box appears. Enter the report title (usually a facility name). The dialog box also contains the Units of Measure radio button for inches/pounds (in/lb) or centimeters/kilograms (cm/kg). Select the desired English or metric units. These settings remain in nVISION until you change them. (Often these settings will be changed only once.)

To Capture Patient Data from a Nonin Pulse Oximeter:

1. Connect the Nonin Pulse Oximeter to the PC using the appropriate serial cable. Check the pulse oximeter operator's manual for more information, or contact Nonin Customer Support.

NOTE: For more information about downloading data, review the pulse oximeter operator's manual or contact Nonin Customer Support.

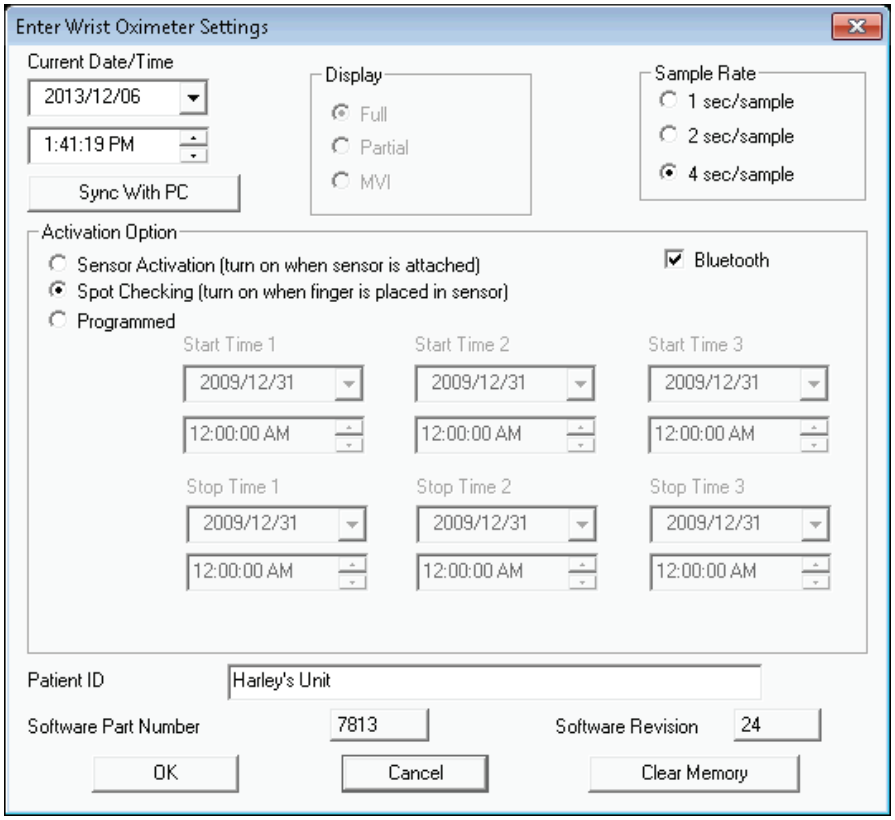
2. Choose New Data Capture from the File pull-down menu, or click on the Data Capture icon on the toolbar. The New Data Capture window appears.



The New Data Capture window has Start, Stop and Cancel buttons to control the download process.

- The Start button tells nVISION that the pulse oximeter will be turned on in memory playback mode.
- The Stop button stops the download when the desired segment has been transferred.
- The Cancel button cancels the new data capture and returns the user to the Main window.

The New Data Capture window also has a Settings button, which is only available when 3100 or 3150 is selected. When you choose Settings, the Enter Wrist Oximeter Settings dialog box appears:

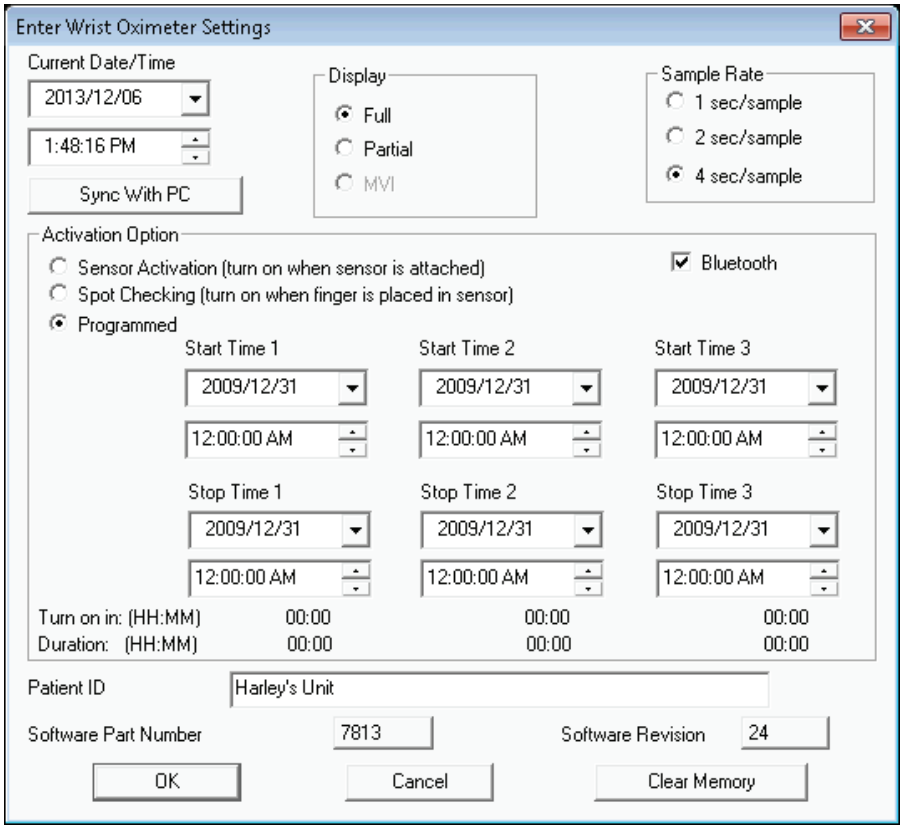


All of the fields of this dialog box are filled in with the current settings of the wrist oximeter. If Spot Checking is selected, the Display field's "Full" and "Partial" options are unavailable.

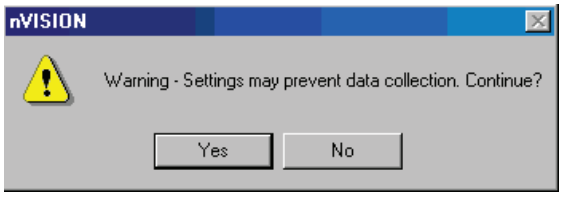
The Bluetooth check box only appears if the 3150 oximeter was selected. If this check box is cleared it will inhibit the Bluetooth radio from turning on to save battery power. Pressing the button on the 3150 will turn the radio back on regardless of this setting. Refer to the 3150 Instructions for Use for more information on the operation of that device.

Current date and time fields are updated every second. When you press the Sync with PC button, the current date and time fields are updated to match the current local time of the PC to which the device is connected.

When you select the Programmed Activation Option, three sets of start and stop times are enabled, allowing you to program the start and stop times for the wrist oximeter:

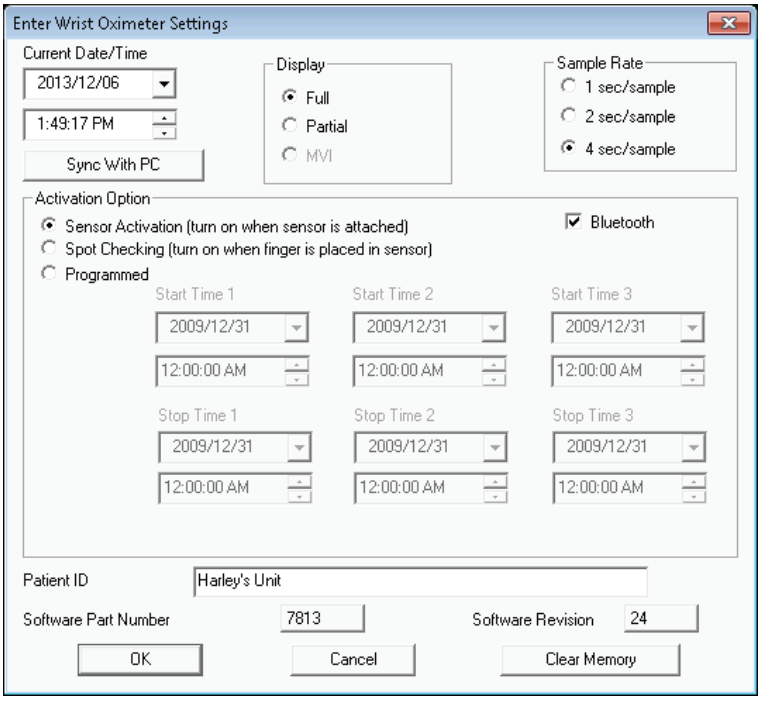


At least one of the intervals selected must have a future stop time selected, with an earlier start time. The device time must be set to at least 1/1/2002. When these conditions are not met, the following dialog box appears:



You may then select Yes or No. If Yes is selected, the settings will be transmitted to the wrist oximeter. If no is selected, you will be returned to the settings option.

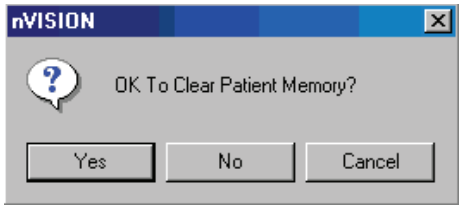
When you select the Sensor Activation Option, the following dialog box appears:



The Display field's "Full" and "Partial" options are available with the Sensor Activation option.

The Settings dialog box contains OK, Cancel, and Clear Memory buttons.

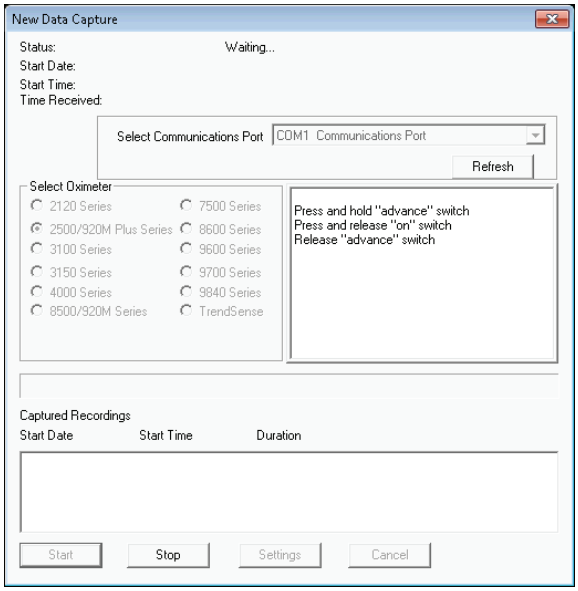
- If you press OK, the current settings are programmed to the wrist oximeter, the dialog box closes, and you are returned to the New Data Capture dialog box.
- If you press Cancel, the current settings are ignored, the dialog box closes, and you are returned to the New Data Capture dialog box.
- If you press Clear Memory, the following dialog box is displayed:



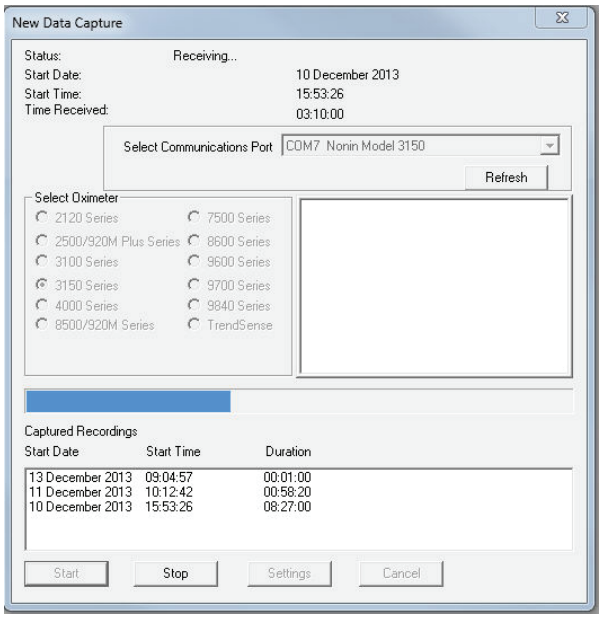
If you select Yes, all wrist oximeter memory is cleared, and you are returned to the Settings dialog box. If you select either No or Cancel, patient data is not cleared, and you are returned to the Settings dialog box.

3. Select your pulse oximeter model by clicking on the corresponding radio button in the Select Oximeter menu.
4. Select the communications port your Oximeter will be transmitting data on. See also Comm Port.
5. Click the Start button at the bottom of the New Data Capture dialog box. (Be sure the pulse oximeter is off before you click the Start button.)

6. Press the correct sequence of buttons on the pulse oximeter, following the specific instructions for your oximeter model, as described in the instructions displayed. The pulse oximeter will download the patient data sets (files) to the PC.



A Status line at the top of the New Data Capture dialog box displays whether or not the nVISION program is receiving data from the device. This status field will display a “Waiting” message until data is received, when it displays a “Receiving” message. Start Date, Start Time, and Time Received fields also appear in the Captured Recording window. In addition, a Percent Completion bar indicates any data transfer in progress.

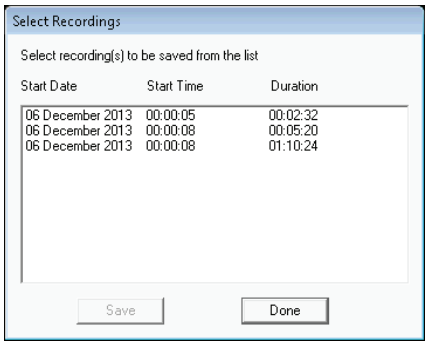


Each data set will appear in the Captured Recordings section after the “data dump” is complete.

After all data from the oximeter are downloaded, the Select Recordings dialog box will appear. The Start Date, Start Time, and Duration of each recorded data segment obtained during the download are displayed in list form in the display window. No data segments will be saved until you select the desired data segment(s), click the Save button, click the New button on the Patient History File dialog box, and finally complete the required patient history information in the Save Data Set dialog box.

Select Recordings for Analysis

After the pulse oximeter finishes downloading or after you click Stop in the New Data Capture dialog box or, the Select Recordings dialog box appears, allowing you to specify which recording(s) you want to save.



nVISION has its own internal database of patient information. You must select the associated patient information to be saved with each captured recording.

NOTE: The Select Recordings dialog box will close automatically when all data sets have been saved. Click on the Done button at the bottom of the Select Recordings dialog box if you do not wish to save any more data segments from the current download session. You will be prompted to click on a Yes, No, or Cancel button.

- Clicking Yes will dispose of the remaining data.
- Clicking No or Cancel will allow you to return to the Select Recordings dialog box.

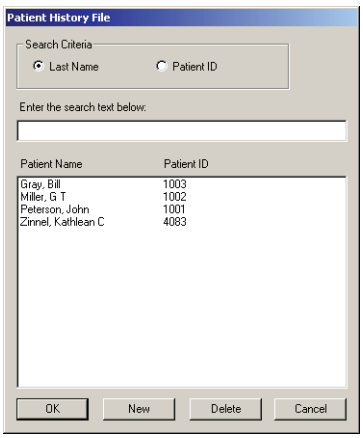
NOTE: All unsaved data segments from a download session will be erased from nVISION if the No or Cancel buttons are clicked. The data remains in the pulse oximeter for future downloads until erased from oximeter memory.

7. Click on the recording(s) you wish to save. The selected recording(s) will be highlighted.

NOTE: In order to merge data sets or recordings that are close together in time, nVISION allows users to select multiple recording to be saved as one data file. The time between recordings will be marked as excluded.

NOTE: When a 3100 or 3150 Wrist Oximeter is used, data sets that have been recorded with different sample rates cannot be merged. This means that when users select the first data set, only data sets that have the same sample rates may also be selected.

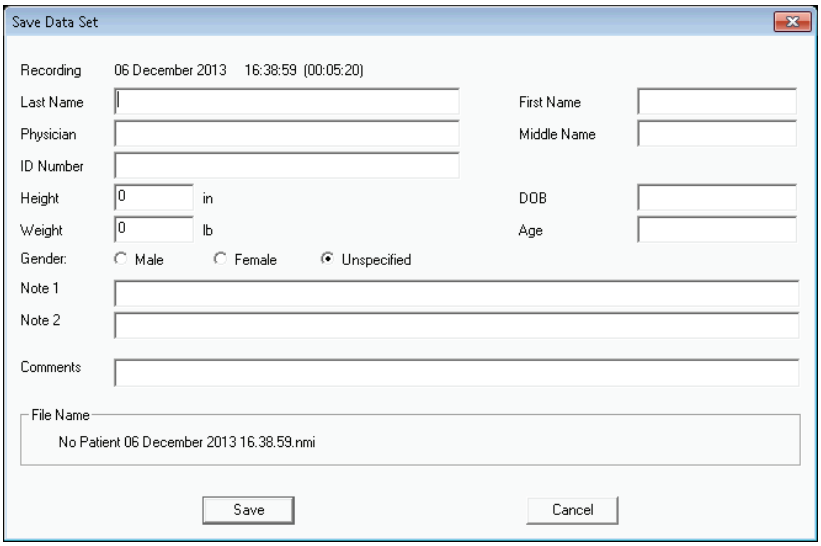
8. Click on the Save button at the bottom of the Select Recordings dialog box.
9. After you click the Save button, the Patient History File dialog box appears. If the patient is new, click the New button at the bottom of the dialog box.



Completing Save Data Set Information—New Patient

The Save Data Set dialog provides space to enter pertinent patient information that will be associated with the specific data set(s) selected in step 7 above. The data set date/time stamp is automatically shown at the top of the dialog box after "Recording."

NOTE: The file name of a recording is comprised of the patient name, date, and time of the recording. If the pulse oximeter's date and time are not set, nVISION uses the date and time set in the PC when the data were downloaded to generate a file name for the data set. This prevents multiple files with identical names.



10. Click in each box to enter patient information, or use your computer Tab key to navigate to the next box. Enter information Last Name, First Name, MI (Middle Initial), Physician, ID Number, Height, Weight, Gender and DOB (Date of Birth). When you enter a DOB, the patient's age is automatically calculated—based on your computer's current system date—and appears in the Age box. If desired, you can enter text in Note 1, Note 2, or Comments fields.

NOTE: If you need to delete all text entered in the Note 1, Note 2, or Comments fields, enter one space (press the Space bar one time) before clicking the Save button.

As you enter text, you will see the new information appearing at the bottom of the Save Data Set dialog box under the File Name display.

NOTE: Date of Birth numbers must be entered in the following format: YYYY/MM/DD.

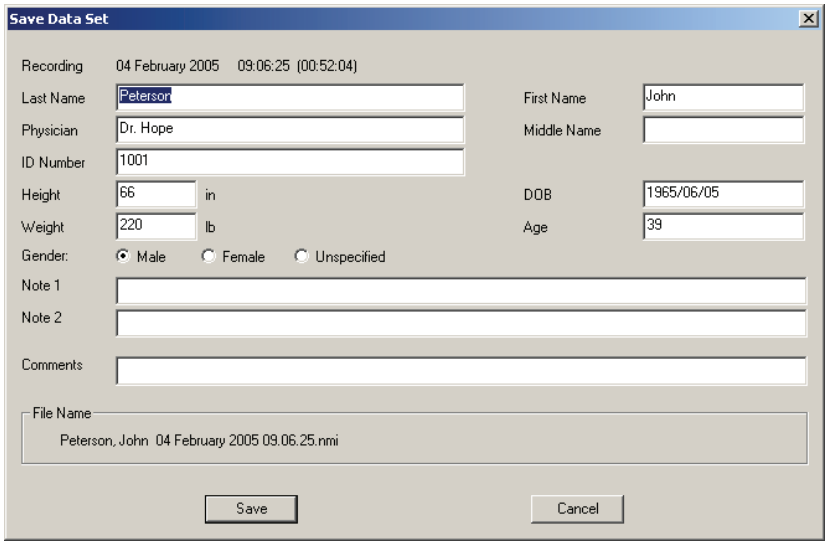
NOTE: "Note 1" and "Note 2" originate from the Patient History file, but they can be changed within a specific patient record when that record is open and is stored as part of the captured recording. Changing Note 1 and Note 2 does not change the Patient History file.

11. When you have finished entering the patient information, click on the Save button at the bottom of the dialog box. The Capture and Save Data sequence is completed. The Save Data Set dialog box disappears and the Select Recordings dialog box reappears if there are any data sets remaining. At this point you may select another data set(s) and begin at step 7 above or click on the Done button to exit Capture/Save Data mode.

NOTE: If you do not click Save, the data set will not be updated.

Completing Save Data Set Information—Existing Patient History file

If the patient's information has already been entered, find the entry in the list and click OK. The Save Data Set dialog box will appear with all the information filled in—except the Comments field, which will allow a unique text string to be associated with each recording.



Tip! If the pulse oximeter is not in playback mode you will see the following error message:

Click OK and begin data capture by selecting New Data Capture from the File pull-down menu, or click on the Data Capture icon on the toolbar. The New Data Capture window will reappear. Turn off the oximeter.

If nVISION is not receiving the downloaded files:

- Check the Comm Port.
- Ensure that you have clicked on the Start button at the bottom of the New Data Capture dialog box.

See Also:

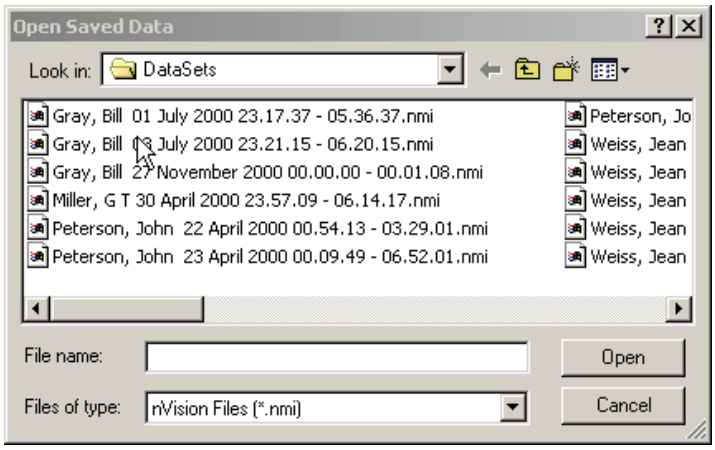
Setup and Use Quick Tour
Comm Port

Data Analysis

Editing Data

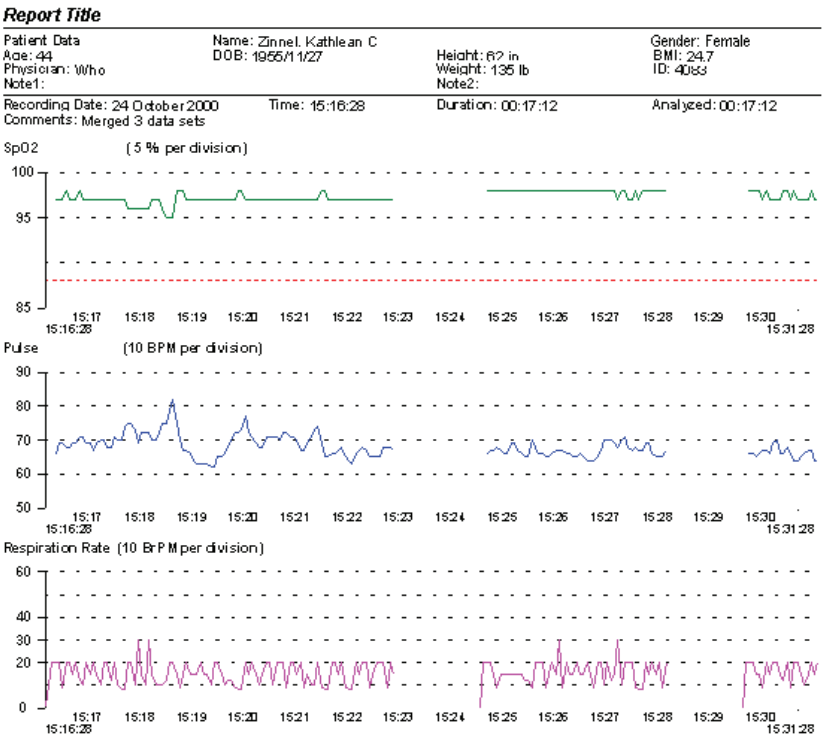
Data Display and Editing Window

The Data Display and Editing window can be opened with either the Open Saved Data command on the File pull-down menu or the corresponding Open Saved Data icon on the toolbar.



In general, data sets are edited before beginning analysis. Double-click on the file name to open a data set for editing. The file opens automatically in the Strip Chart Report, showing the raw data acquired from a Nonin pulse oximeter.

NOTE: Events are indicated by a black bar above the graph, and they correspond to the data directly below the bar.



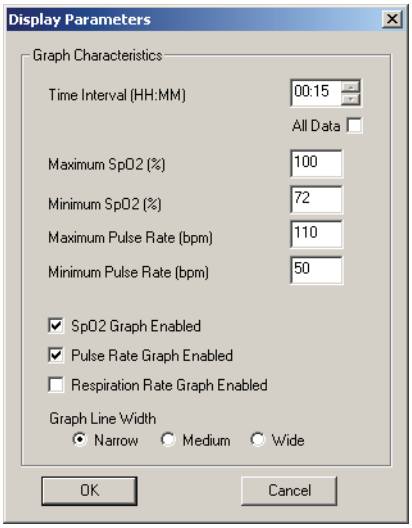
A graphic display of the SpO2 data stacked over the pulse rate data (along a timeline) allows the user to evaluate data, identify and exclude noisy artifact data, and select the type of analysis. The name of the file associated with the data is displayed at the top of the report under "Patient Data."

NOTE: You have the option to change the Report Title. Choose the Report Title command from the Report menu. A dialog box appears. Enter the report title (usually a hospital or facility name). The dialog box also contains the Units of Measure radio button for in/lb or cm/kg. Select the desired English or metric units.

Editing data is a two step process. First, you must adjust the Display Parameters of the Report display to your desired values in order to format the Full Study Report. Then, you must identify and exclude noisy artifact data.

Adjusting Display Parameters

After selecting the Display Parameters command or clicking the Display Parameters icon on the toolbar, the Display Parameters dialog box appears:



- When All Data is checked, the x-axis is automatically adjusted so that all data fits on the screen at one time when viewed with the Strip Chart Report or printed with the Full Study Report.

The Display Parameters command is used to achieve the desired data resolution and to print specific patient data. The Analysis Parameters command is used to set the desired event-marking criteria.

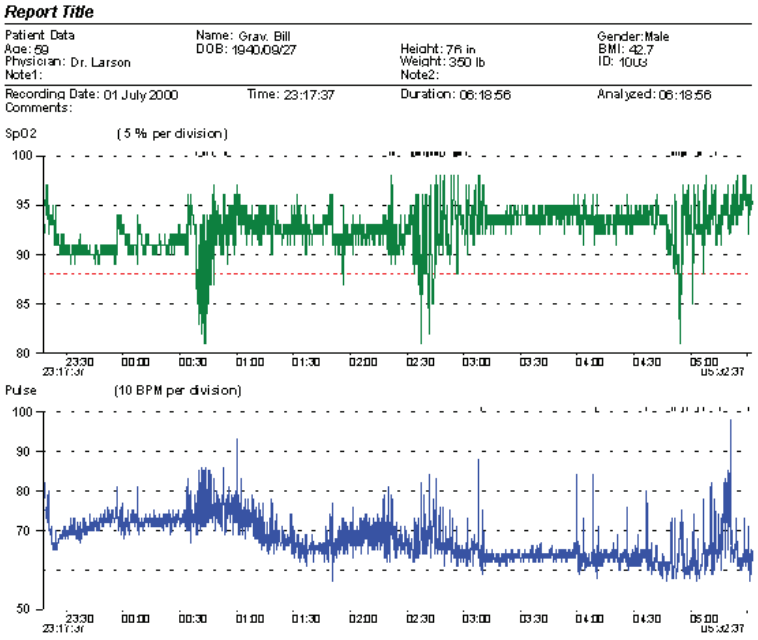
1. Click on the All Data check box to disable that function.
2. You may edit the Time Interval; the maximum and minimum SpO2, and the Pulse Rate figures at this point to expand or contract the scale in order to more accurately assess points of noisy data.

NOTE: The edited Time Interval is shown as Display time in the lower left corner of the window.

3. Click on the Respiration Rate Graph Enabled check box to disable that function.

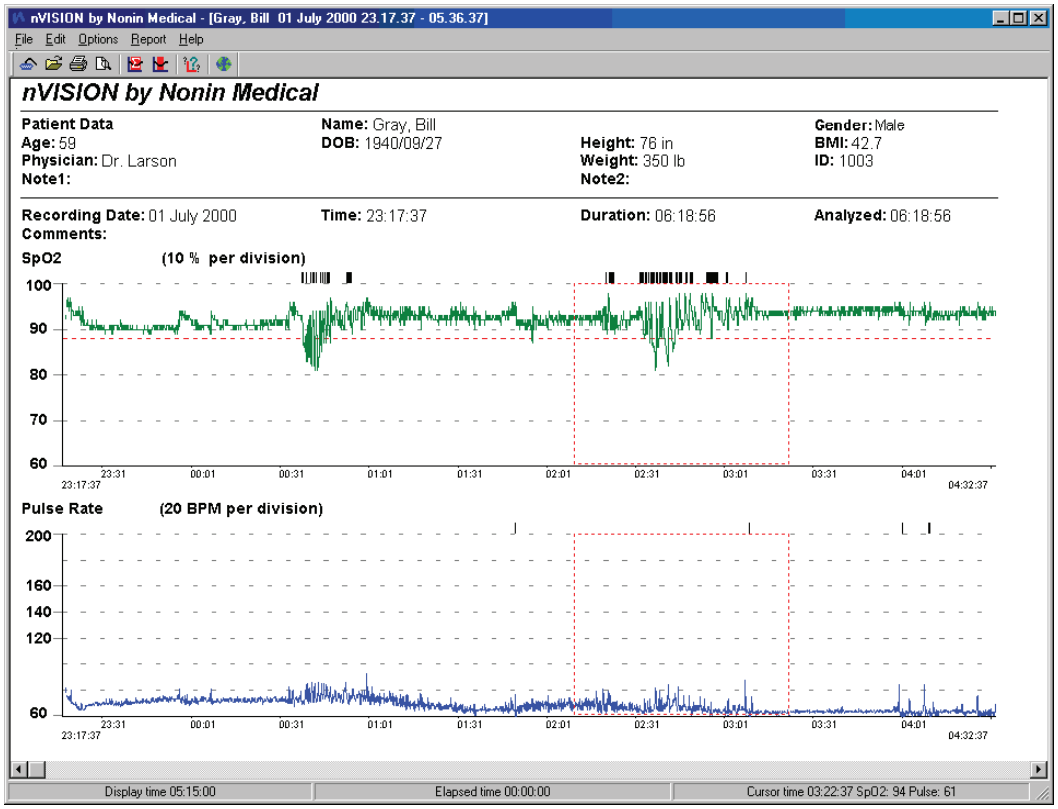
NOTE: For oximeters with respiration rate information, do not disable the Respiration Rate Graph Enabled check box.

4. Click OK to save changes to the display. (When Cancel is selected, any changes made to the display parameters are lost.) The Strip Chart Report now reflects changes made.



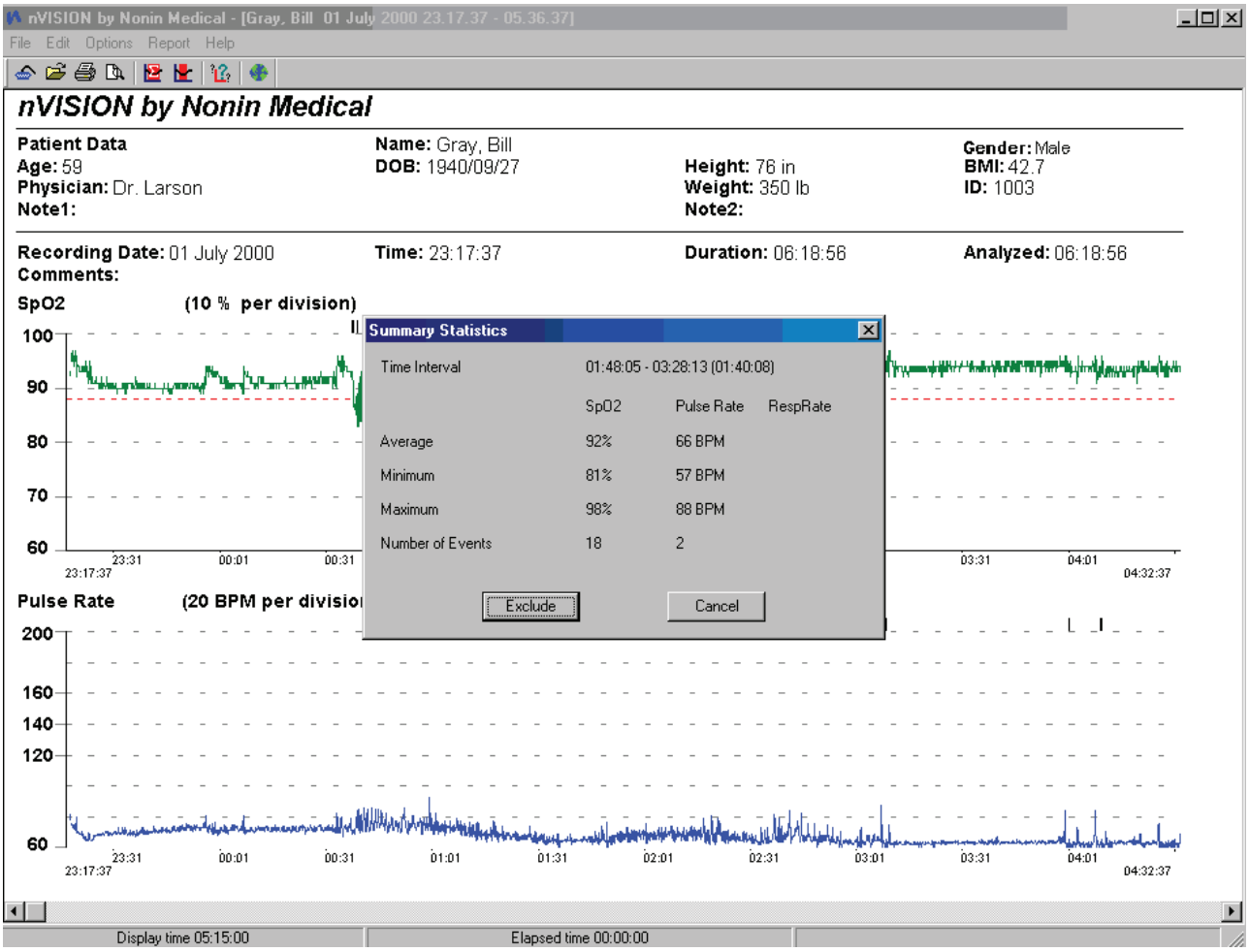
Identifying and Excluding Data

1. Place the cursor on any graph point. Right-clicking displays the time of the graph point and data values at bottom right of window.



2. Use the scroll button, arrow keys, or Page Up and Page Down keys to navigate through the graphed data.
3. Place the cursor before data to be excluded, left-click the mouse, and hold and drag to the point after the artifact data. A red dashed-line rectangle appears and encloses the data area. If you click inside that enclosed area, you see the selected time interval at the bottom right of window.

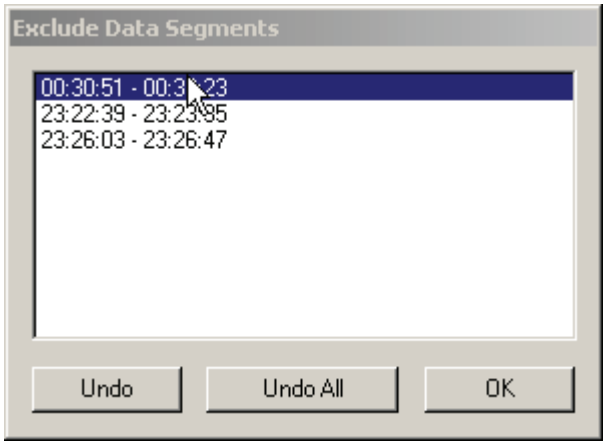
To review the enclosed area statistics in more detail before excluding the data, select Summarize Data from the Edit pull-down menu or click on the icon . The Summary Statistics dialog box appears:



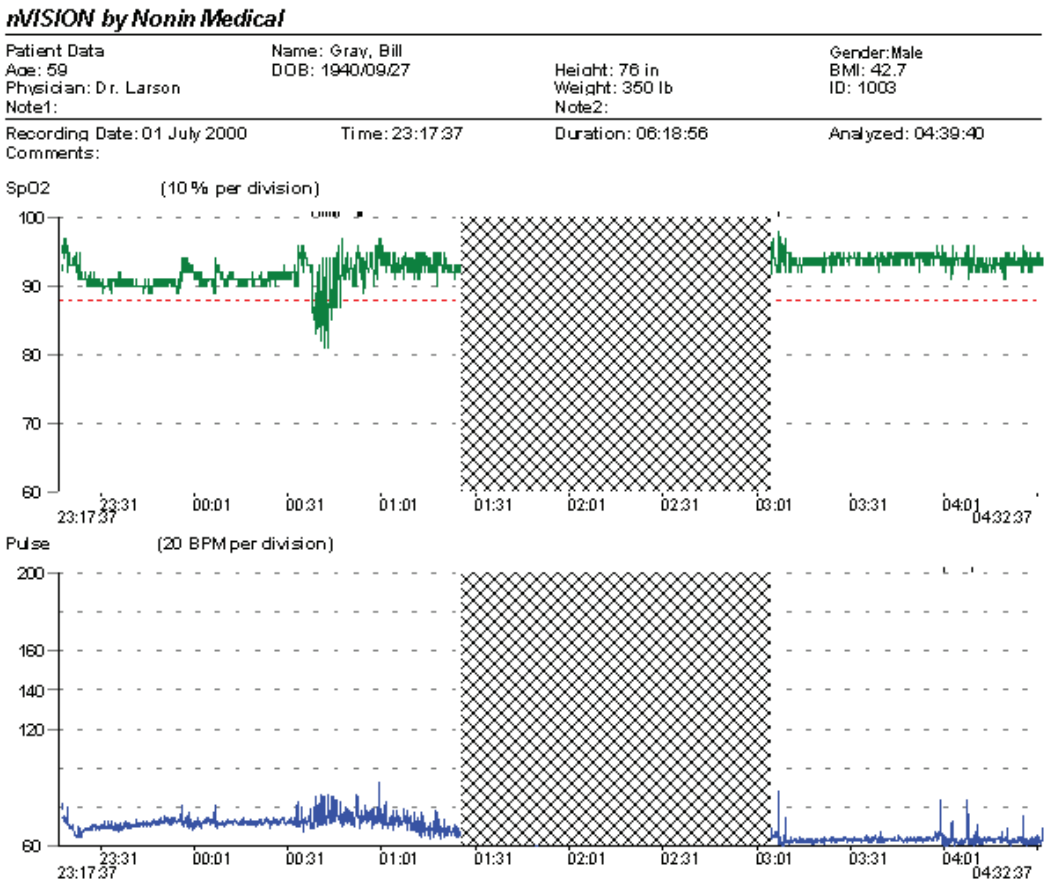
Click the Exclude button to accept the data selection. Click the Cancel button to return to the displayed Strip Chart report.

NOTE: The Summary Statistics dialog box will display Respiratory Rate data even if it is not displayed on screen if this data is part of the saved data set file.

You can exclude data directly by following steps 1 through 3 above and then selecting Exclude Data from the Edit pull-down menu or by clicking on the icon . This brings up the Exclude Data dialog box.



Click OK to save the excluded data segment. The area is now marked with a crosshatched pattern.



You can undo any or all selected data sequences by clicking Undo or Undo All on the Exclude Data dialog box.

After excluding all noisy data desired, select Save or Save As under the File pull-down menu to retain these edits with the raw data.

Analyzing Data

After the mechanics of capturing and saving data, etc., analyzing data is primarily adjusting parameters so that the resulting event determination and statistics make sense.

Before you get to this stage, you may have done the following for a particular recording:

- Downloaded data from a pulse oximeter
- Saved the recording to the Data Sets folder
- Adjusted the Display Parameters
- Adjusted the Analysis Parameters

The Analysis Parameters command is under the Options pull-down menu. The Analysis Parameters command allows the user to select SpO2 Parameters, Pulse Rate Parameters, and Respiratory Pause Parameters (when available).

For detailed information about setting and changing Analysis Parameters, see Analysis Parameters.

Report Considerations

You can see the effects of adjusted parameters by reviewing the Oximetry Report.

1. Open a saved data set by choosing Open Saved Data from the File pull-down menu or choosing the OPEN icon  from the toolbar. The Strip Chart Report automatically opens.
2. Select Display Parameters and Edit Data to exclude noisy or suspect data.
3. Select Oximetry Report from the Report pull-down menu. The Index number under Event Data is the most important value because events per hour are used as a diagnostic aid. The Adjusted Index number under Event Data is calculated after excluded data are removed from the analysis.
4. If new case-specific analysis parameters were used, the user may wish to save the recording again or save it as a new recording (using the Save As command from the File pull-down menu).

See Also:

Capturing and Saving Data
Editing Data

Data Reports

Report Descriptions

Six reports are available from the Report pull-down menu: Oximetry, Strip Chart, Full Study, Respiration Rate, Summary, and 6 Minute Walk Reports.

General Overview

- SpO2 data is graphically displayed in green on the SpO2 graph, pulse rate data is graphically displayed in blue, and (when available) respiratory rate data is displayed in violet on the Respiration Rate report.
- On the SpO2 graph, a gray dashed guide line is spaced every 10 percent—or every 5 percent if the minimum and maximum SpO2 values are less than or equal to 20 percent apart.
- On the Pulse Rate graph, a gray dashed guide line is spaced every 10 beats per minute (BPM)—or every 20 BPM if the minimum and maximum pulse rate values are >100 BPM apart.
- On the Respiration Rate graph, a gray dashed guide line is spaced every 10 beats per minute (BPM).

Oximetry Report

The Oximetry Report provides a convenient data summary of the patient during the monitoring period. The Oximetry Report is a one-page summary that focuses primarily on event data as defined by the analysis parameters. The report is divided into four sections:

- Patient Data
- Numerical Data Summary - Detailed event data, %SpO2 data, and pulse rate data.
- Analysis Parameters - Parameters used to analyze the data set and calculate and report events.
- Graphic Summary - Includes a number of graphic summaries, including SpO2 data, detected SpO2 events, pulse rate data, detected pulse rate events, and time. Events are calculated as defined by the analysis parameters and are indicated with black vertical lines below the timeline. A red dashed guide line on the SpO2 graph indicates the threshold as set by desaturation event criteria (an analysis parameter).

Strip Chart Report

The Strip Chart Report is the default report that appears when a data set is opened by nVISION. Its best uses are viewing, analyzing, and editing data. In addition, this report provides the convenience of summarizing a specific block of data or interrogating a specific data point within any data set.

The Strip Chart Report, which is displayed on the screen horizontally, provides a detailed graphical representation of SpO2, pulse rate, and respiration rate data (when applicable), where time is indicated on the x-axis of each graph.

Events are calculated by user-defined analysis parameters and are indicated with black bars above the data in each respective graph.

In the Strip Chart Report, Display Time (as set in the Display Parameters dialog box) is indicated in the lower left-hand portion of the status bar. The area at the center of the status bar is Elapsed Time, which is updated as you scroll through the report (using the arrows on the scroll bar or on the keyboard). Use the right mouse button to display specific data at the cursor point in the lower left-hand region of the status bar.

Use the arrow keys on the keyboard or the arrow symbols on each side of the scroll bar to navigate the Strip Chart Report.

NOTE: In order for stored data to correlate to a 24-hour clock (international time), the time and date must be set in the pulse oximeter before recording patient data. If time and date were not set in the pulse oximeter before recording patient data, nVISION will automatically assign the time of download, as set in the PC, as the time associated with that data set.

NOTE: The Strip Chart Report will print 1 page of on-screen data, providing users with a convenient method for documenting specific data sections.

Full Study Report

The Full Study Report, provides full graphical representations all of the data—arranged on as many pages as it take to print that data to the scale selected in the Display Parameters dialog box. The Full Study Report is displayed on-screen vertically, and users scroll through the data using the Page Up/Page Down Keys or the scroll bar on the right side of the screen.

Crosshatched patterns are indicated on the graphs to document segments excluded from analysis.

Respiration Rate Report

The Respiration Rate Report provides respiration rate data for the patient during the monitoring period. In addition to respiration rate data, the Respiration Rate Report provides summaries of respiratory pause data, a graphic summary of all data, and a bar graph of respiration rate frequency distribution.

NOTE: The Respiration Rate Report is only available when patient respiration data is gathered from appropriate Nonin devices.

NOTE: You can turn the Respiratory Rate display on the Strip Chart on and off using the Display Parameters command from the Options pull-down menu.

Summary Report

The Summary Report provides a convenient data summary of the patient data during the monitoring period. The Summary Report is a one-page summary that focuses primarily on event data as defined by the analysis parameters. The report is divided into six sections:

- Patient Data
- Numerical Data Summary - Detailed event, %SpO2, and pulse rate data.
- Analysis Parameters - Parameters used to analyze the data set and calculate and report events.
- Graphic Summary - Includes a graphic summary of SpO2 and pulse rate data if selected by the display settings. A red dashed line on the SpO2 graph indicates the threshold as set by desaturation event criteria (an analysis parameter).
- Interpretation Area - A place for reviewer comments.
- Physician Signature Block - Allows documentation for insurance and record-keeping purposes.

6-Minute Walk Report

The 6-Minute Walk Report provides a convenient form for six minute walk studies. It has fields that can be modified by double clicking on the report and can display data in either 30 second or one minute intervals. It lists all data points on subsequent pages after the initial report.

Printing Reports

Use the following procedure to print reports using nVISION software:

- Press the Print icon on the toolbar.

–or-

- Select Print from the File pull-down menu.

The Print dialog box appears when either of these printing methods is used. Make the appropriate printing selections from the Print dialog box, and then press OK to print the report(s).

nVISION offers a Print Setup command, which includes networked and local printers, as part of the File pull-down menu. For previewing reports, a Print Preview icon on the toolbar allows the user to view the report as it would appear when printed.

See Also:
Report Descriptions

Tutorial

Introduction

This section provides a detailed patient tutorial to help you become familiar with nVISION software. For a basic introduction to nVISION, see the Overview of nVISION and the Setup and Use Quick Tour.

NOTE: Please print a paper copy of this tutorial to use while learning nVISION software.

Ten sample data sets (patient case studies) are provided with nVISION software.

- Six case studies contain pulse oximetry data (SpO2 and pulse rate information).
- The seventh case contains pulse oximetry data and respiration rate data.

These sample case studies are provided for your convenience—so that you can manipulate the patient data and practice using nVISION. We will use only one of these sample data sets to walk through this tutorial.

To access the sample data sets, select the Open Saved Data command from the File pull-down menu. For this tutorial, click on the file named "GT Miller 30 Apr 2000 23.57.09-06.14.17," and then click on Open.

Strip Chart Report

To prepare the new data for analysis, select Strip Chart from the Report pull-down menu.

The Strip Chart Report provides a graphical representation of data (in this case, SpO2 and pulse rate). The time is indicated on the x-axis of each graph. An "event" is calculated by applying the user-selected, case-specific analysis parameters. Events are indicated by a black mark above the data in each graph.

Notice in the Strip Chart Report that "Display Time" is indicated in the lower left side of the status bar, as set in the Time Interval section of the Display Parameters screen. (Check that the All Data check box within the Display Parameters screen is not checked.) At the center of the status bar is "Elapsed Time." Notice that the elapsed time is updated as you scroll through the report (using the arrows on the scroll bar or on the keyboard.) The right side of the status bar displays data values when the user right-clicks on the data graph.

NOTE: In order for stored data to correlate to a 24-hour clock (international time), the time and date must be set in the pulse oximeter before recording patient data. If time and date are not set in the pulse oximeter before recording patient data, nVISION will automatically assign the time set in the PC, as the time associated with the data.

Scroll from the beginning to the end of the report. Use the arrow keys on the keyboard, or click on the arrow symbols on the scroll bar.

For review purposes, we will analyze specific sections in greater detail. Select Display Parameters from the Options pull-down menu, or click on the Display Parameters icon  on the toolbar. The settings for each display item appear.

Change the parameter values by highlighting the current numerical value in each box and entering the new value. Use your computer's Tab key to move to the next field, or simply click in that field.

NOTE: If the Num Lock key is OFF on the keyboard, the keypad will not be active.

1. De-select the checkbox marked "All Data."
2. Set the Time Interval by keying in "01:00." The Time Interval indicates the amount of data (in hours and minutes) that will be displayed on the screen (in this case, 1 hour of data will be displayed).
3. Enter the Maximum SpO2 of "98."
4. Enter the Minimum SpO2 (%) of "70."

5. Enter the Maximum Pulse Rate of "140."
6. Enter the Minimum Pulse Rate of "60."
7. Click on OK.

Notice that two SpO2 events and three Pulse Rate events are indicated on the screen for the first hour of this study. (See section on setting Analysis Parameters for further information.)

Editing Data (Excluding and Summarizing Data)

A marker is available in this report (indicated by a red, dashed-line rectangle). The marker can be used to identify a specific block of data, to review a statistical summary of data within the rectangle, and to identify and mark areas of artifact (noisy data) to be excluded from the analysis.

NOTE: Excluded data are identified by crosshatched patterns. Excluded data are not excluded from any report. On the Oximetry Report, excluded data are included in the calculation of % Artifact. Excluded data are not used in any other calculations on the Oximetry Report. Analyzed Time has the excluded data subtracted from the Duration.

To obtain the vertical marker, click and drag within either the SpO2 or Pulse Rate graphs. You will notice that when you click and drag the mouse, a rectangle is created in both the SpO2 and Pulse Rate graphs. The size of the rectangle changes as the mouse is moved to the left or right.

For this review, click and hold the mouse within the Pulse Rate graph beginning at minute 6 and releasing at minute 11.

To obtain statistical summary information about the data, click on the Summarize icon or select Summarize from the Edit menu. Notice that the statistical summary of the patient's data for this rectangle is shown. You will also notice that you can exclude data segment(s) from this dialog box. Click on Exclude, and then click on OK.

Another way to exclude data segment(s) is by using the Exclude icon on the toolbar. For this review, click and hold the mouse within the Pulse Rate graph, beginning at minute 21 and releasing at minute 26. After clicking and dragging the mouse to create a rectangle, click on the Exclude icon and click on OK. Alternatively, you may select Exclude Data from the Edit menu, and then click on OK.

To clear or undo the excluded data, click on the Exclude icon, or select Exclude Data from the Edit menu. In the Exclude Data Segments dialog box, click on Undo All to undo all excluded data, or click on the desired data segment (for this example "00:06:01 – 00:11:01"). Notice the data segment is now highlighted. Click on Undo.

NOTE: The crosshatched pattern is removed when excluded data is cleared (not excluded).

Oximetry Report

We begin by reviewing the Oximetry Report. Select Oximetry Report from the Report menu.

The Oximetry Report provides a good overview—using case-specific analysis parameters—of the patient during the monitoring period. The report is divided into four sections.

- Patient Data
- Numerical Data Summary, with detailed event data, %SpO2 data, and pulse rate data
- Analysis parameters (parameters used to analyze patient data)
- Graphic summary

The Oximetry Report includes a number of graphic summaries:

- First is a graphical representation of the patient's SpO2 data.
- Directly under this graph is a summary of detected SpO2 events (identified by vertical bars).
- Next is a graphical representation of the patient's pulse rate data.
- Directly under this graph is a summary of detected pulse events (identified by vertical bars).
- Time is indicated under the last graphic summary (in this case, the Pulse Rate graph). Time is marked to the nearest hour.

At the bottom of the page are the SpO2 summary histograms.

- On the left is the % time spent at SpO2 level—the percent time distribution at a given SpO2 level, over the monitoring period. Notice that the y-axis is labeled % Time and the x-axis is labeled SpO2 value (100-30%). Note the correlation between the basal SpO2 value of 94%—located in the numerical summary near the top of the report—and this graph.
- On the right is the number of SpO2 events—by SpO2 level, in 5 percent increments. Note the correlation of %SpO2 level in the numerical event data summary near the top of the report with the events identified to the distribution summary of events: 15 events @ 94-90 %SpO2—indicated by a shorter bar in the graph, 24 events @ 89-85 %SpO2—indicated by a higher bar in the graph.

Full Study Report

A Full Study Report is also available through nVISION; however for this review, it will not be discussed in detail. As its name implies, the Full Study Report provides full graphical representations of the data. When Print is selected in this report, all pages will print according to the display interval selected from the Display Parameters dialog box.

Summary Report

The Summary Report can be selected from the Report pull-down menu. The Summary Report provides a good overview—using case-specific analysis parameters—of the patient during the monitoring period. The report is divided into four sections:

- Patient Data
- Numerical Data Summary, with detailed event data, %SpO2 data, and pulse rate data
- Analysis parameters (parameters used to analyze patient data)
- Graphic summary

The Summary Report includes a number of graphic summaries:

- First is a graphical representation of the patient's SpO2 data.
- Directly under this graph is a summary of detected SpO2 events (identified by vertical bars).
- Next is a graphical representation of the patient's pulse rate data.
- Directly under this graph is a summary of detected pulse events (identified by vertical bars).
- Time is indicated under the last graphic summary (in this case, the Pulse Rate graph). Time is marked to the nearest hour.

In addition, the Summary Report includes an Interpretation Area (for reviewer comments) and a Physician Signature Block (for insurance and record-keeping purposes).

Saving Data

In order to save the changes you made to the data set (i.e., any editing, changes to the analysis parameters, etc.), you must save the changes before closing the file. To save data to the same file name, select Save from the File pull-down menu. Selecting Save As from the File pull-down menu will allow you to save the edited file under a different name if you do not wish to overwrite the original data.

NOTE: If the data set is closed before saving the changes, the data set will revert to the original or most recently saved data.

Conclusion

Nonin Medical Inc. hopes that the overview information provided in this tutorial has provided useful information that will allow you to more comfortably explore the unique features of nVISION software.

See Also:

Overview of nVISION
Capturing and Saving Data
Editing Data
Analyzing Data
Printing Reports

Glossary

A

Term	Definition
adjusted index	A key sleep screening statistic, calculated as events per hour of "analyzed data" (that is, a data set minus any excluded data). "Raw" and "adjusted" index values are included in the Event Data reporting block of the Oximetry Report. For example, if a patient's recording contains 300 events over a recording period of 4 hours, and 1 hour of data is excluded, the Adjusted Index is calculated as follows: 300/3 = 100 (events/hour)
all data	A check box in the Display Parameters dialog box. When the All Data check box is selected, the entire data set will be displayed in the Strip Chart Report. (The Time Interval [HH:MM] option is disabled).
analysis parameters	Analysis parameters define the criteria by which events are detected and reported.
% artifact	A parameter found on the Oximetry Report. The percent of time data were missing or excluded. For example, if the study is 6 hours long, and 1 hour is determined to be artifact, the % Artifact is calculated as follows: 1/6 = 16%
ASCII file	American Standard Code for Information Interchange. A format that allows you to save data to be read into other programs (e.g., Excel) for further analysis.
average	Sum of the data value divided by the number of data points.
avg. event dur. (sec)	Average event duration, which is average time in seconds per event.
avg. low SpO2 (%)	Average of lowest SpO2 seen over all events.
avg. low SpO2 < 88%	The average of lowest SpO2 seen over all events where the drop exceeded the special desaturation criteria level.
avg. pulse rate (BPM)	Found in the Pulse Data summary section of the Oximetry Report, the average pulse rate is the average beats per minute of the heart during the measured time period.
avg. respiration rate (BrPM)	The average respiration rate is the average breaths per minute recorded during the data set.

B

Term	Definition
basal SpO2 (%)	Steady-state SpO2. The basal SpO2 is the average of the SpO2 readings that are not included in any desaturation event. The basal SpO2 is displayed on the Oximetry Report.
BMI	Body mass index.
body mass index (BMI)	A body measurement that takes only height and weight into account. A method of determining caloric nutritional status. Body mass index is calculated as follows: BMI = weight (kg)/height (m)2 A BMI over 25 is an indication of overweight; this may be a risk factor for sleep apnea episodes. Because BMI does not consider lean body mass, its results are usually most reliable for non-athletes.
BPM	Beats per minute—a measure of pulse rate. BPM should not be confused with breaths per minute (BrPM).
BrPM	Breaths per minute–a measure of respiration. BrPM should not be confused with beats per minute (BPM)

C

Term	Definition
capnography	The monitoring of the concentration or partial pressure of carbon dioxide in the respiratory gases.
capture	When the oximeter plays back patient data from memory, the PC will catch the data coming in over the serial communications port.
case study	An example based on real data used for teaching or analysis. Also called "data set" within this Help file.
comm port	Communications port. A port on the computer where the serial cable is attached. You can choose the Communications Port setting by selecting Comm Port under the Options pull-down menu.
comma-separated value file	An ASCII file with the data values separated by commas, with one line for each sample. (For example, the format would look like xx, yy, zz, ...)
communications port (comm port)	A port on the computer where the serial cable is attached. Often called a "comm port." You can choose the Communications Port setting using the Comm Port command under the Options pull-down menu.
configure communications port	A dialog box that appears when the Comm Port command under the Options pull-down menu is selected. You can choose the computer serial cable connection setting using the Comm Port command.
cursor time	Cursor Time (in HH:MM:SS) is displayed at the bottom of the Data Display and Editing Window when the cursor is dragged across a Strip Chart Report to select a time interval to exclude or summarize.
Customer Support	Phone: 1.800.356.8874 (USA and Canada only) +1.763.553.9968 +31 (0)13 - 79 99 040 (Europe) Fax: +1.763.553.7807 +31 (0)13 - 79 99 042 (Europe) E-mail: technicalservice@nonin.com technicalserviceintl@nonin.com Web: nonin.com Mailing address: **Nonin Medical, Inc.** 13700 1st Avenue North Plymouth, MN 55441-5443, U.S.A. **Nonin Medical B.V.** Prins Hendriklaan 26 1075 BD Amsterdam, Netherlands NOTE: When calling Nonin Customer Support, you will be asked to provide the nVISION software key code, which is displayed in the About nVISION window, and is also printed on the nVISION CD-ROM jacket.

D

Term	Definition
data capture	To download or retrieve data from a Nonin pulse oximeter using nVISION Software.
data display and editing window	The Strip Chart Report window allows the user to adjust the display parameters for the full report and to exclude noisy or otherwise suspect data from analysis.
data path	A command, located under the Options pull-down menu, that allows you to select the folder where nVISION data is stored.

Term	Definition
data set	A single captured recording file. Also called "case study" within this Help file.
data storage path	A command, located under the Options menu, that allows you to select the folder where nVISION data is stored.
default setting	When the user chooses Defaults, all parameters will be set to other preset values. Example: Choosing defaults with Case Specific Analysis Parameters will set them to the System Analysis Parameters.
desaturation	When SpO2 shows a decreasing trend.
desaturation criteria level	A value that is set using the Analysis Parameters command.
desaturation event	Defined by values set using the Analysis Parameters command. Both Percent Drop for Event (%) and Minimum Event Duration (sec) criteria must be met in order for an event to appear (graphically shown as a solid black bar).
directory	A specific location within a computer server or hard drive. For example, nVISION users can import an exported data set from an ASCII file into the "DataSets" directory and the patient history database.
display parameters	Parameter items set up or modified to obtain desired report output. Selecting the Display Parameters command from the Options pull-down menu brings up a dialog box to adjust the scales for viewing the data. Through this dialog box, you can select how much time on the x-axis will fit in the window and adjust the range of values for pulse rate, saturation, or respiration rate on the y-axis.
display time	The length of time currently displayed on a single screen in the Strip Chart Report.
DOB	Date of Birth. This data must be entered in the format "YYYY/MM/DD". (For example: 1977/04/05.)
download	To capture or retrieve data from a Nonin pulse oximeter using nVISION Software.
duration (dur)	The length of time of a captured recording or event.

E

Term	Definition
edit	To change or update program parameters. The Edit menu includes Summarize Data, Exclude Data, Patient Info, and Patient History File. These commands contain information that can be changed or updated.
edit menu	See Edit Menu Commands
elapsed time	The length of time that has passed in the captured recording to get to the data shown in the window of the Strip Chart Recording.
event	A pattern in the recorded data that provides objective documentation that a sleep disorder might be present. The pulse rate must exceed both the rate change and the event duration criteria to qualify as an event. The saturation must drop more than the percentage change criteria and exceed the minimum duration criteria to qualify as an event.
event data	The event data block presents summary statistics for both pulse rate and %SpO2.
event distribution	A way of summarizing event data to look at the dispersion pattern of low SpO2 and duration.
event duration	The length of time that an event lasts.
exclude	To remove, eliminate, or reject suspect data from the analysis.
exclude data	To remove, eliminate, or reject suspect data from the analysis.
exclude data segments	A list box that allows the user to arrange excluded data during analysis.
exit	The Exit command is under the File pull-down menu. When Exit is selected, the nVISION program will terminate.

Term	Definition
export	The Export command allows you to export data from nVISION to a comma-separated value file, so it can be read into a spreadsheet program such as Microsoft Excel or Lotus 1-2-3. Selecting Export from the File pull-down menu allows you to write the currently open data set to an ASCII file. This allows you to save the data in a form that can be read into a spreadsheet program for further analysis. The Export command converts a data set from the internal format to a fixed format ASCII character file, where the individual data fields are separated by commas.

F

Term	Definition
file menu	See File Menu Commands
full study report	The Full Study Report provides full graphical representations all of the data—arranged on as many pages as it take to print that data to the scale selected in the Display Parameters dialog box. The Full Study Report is displayed on-screen vertically, and users scroll through the data using the Page Up/Page Down keys or the scroll bar on the right side of the screen. Crosshatched patterns are indicated on the graphs to show segments excluded from analysis.

H

Term	Definition
help	nVISION Software comes with an online Help system to help you use the software. To Use nVISION Help: 1. Select Help Topics from the Help menu. 2. Choose the Contents tab to review the table of contents. -or- Choose the Index tab to search the index entries. -or- Choose the Find tab to search for specific entries in the Help Topics.
help menu	The Help menu includes Help Topics and About nVISION. The Help menu allows users to access the nVISION Help system.
help topics	The Help Topics command is under the Help menu. When the Help Topics command is selected, a dialog box with Contents, Index, and Find tabs appears.

I

Term	Definition
ID number	Patient identification number. This number can be any user-defined number, or it can be left blank if desired.
import	The Import command allows you to import data that has previously been exported from nVISION. Selecting Import from the File pull-down menu allows you to import an exported data set from an ASCII file into the “DataSets” directory and the patient history database.
index	A key sleep study statistic, calculated as events per hour. “Raw” and “adjusted” index values are included in the Event Data reporting block of the Oximetry Report.

K

Term	Definition
key code	The software key code printed on the nVISION CD-ROM jacket. The key code is entered during nVISION Software installation and is displayed in the About nVISION window. During the nVISION Software installation process, the install program will ask for a key code. The installation will not proceed if an invalid key code is entered. (The key code must be entered as it appears—including dashes.) When calling Nonin Technical Support, the user will be asked to provide this key code.

L

Term	Definition
language	A command under the Options pull-down menu that allows you to change the language used in reports, menus, etc.
left-click	Click using the left mouse button.
low pulse rate (BPM)	A statistic displayed on the Oximetry Report that defines the single lowest pulse rate in the recording.

M

Term	Definition
main window	The Main window allows selection of the functions needed for data capture, editing of data sets, analysis, or report printing.
maximum pulse rate (BPM)	A parameter in the Display Parameters dialog box that sets the value shown at the top of the y-axis for pulse rate graphs.
maximum SpO2(%)	A parameter in the Display Parameters dialog box that sets the value shown at the top of the y-axis for SpO2 graphs.
min. SpO2(%)	Lowest single SpO2 value seen. This parameter is displayed in the Oximetry Report.
min. respiration rate (BrPM)	Lowest single respiration rate value seen. This parameter is displayed on the Respiration Rate Report.
minimum event duration (sec)	Values that are set using the Analysis Parameters command; the minimum duration (which is measured in seconds) must be exceeded to qualify as an SpO2 or pulse rate event.
minimum pulse rate (bpm)	A parameter in the Display Parameters dialog box that sets the value shown at the bottom of the y-axis for pulse rate data graphs.
minimum SpO2(%)	A parameter in the Display Parameters dialog box that sets the value shown at the bottom of the y-axis for SpO2 data graphs.

N

Term	Definition
new data capture	The New Data Capture command, which is located under the File pull-down menu, is used to capture and download data sets from Nonin pulse oximeters.
nmi files	The file type suffix (.nmi) added to Nonin Oximetry data files. (Literally: Nonin Medical, Inc.)

O

Term	Definition
open saved data	Using the Open Saved Data command under the File pull-down menu allows users to open a saved data set.
options menu	See Options Menu Commands. The commands in the Options menu allow the user to configure several nVISION parameters. The selected configuration options are saved by nVISION. If no settings are changed by the user, nVISION will use the default configuration.
oximeter	A pulse oximeter. A device that measures blood oxygen saturation (%SpO2) and pulse rate.
oximetry report	The Oximetry Report provides an overview—using user-defined analysis parameter settings—of the patient during the monitoring period. The Oximetry Report is a one-page summary that focuses primarily on event data as defined by the analysis parameters. The report is divided into four sections: • Patient Data • Numerical Data Summary, with detailed event data, %SpO2 data, and pulse rate data • Analysis parameters (parameters used to analyze patient data and calculate events) • Graphic summaries The Oximetry Report includes a number of graphic summaries, including SpO2 data, detected SpO2 events, pulse rate data, detected pulse rate events, and time. Events are calculated by user-defined analysis parameters and are indicated with vertical black lines below the data in each respective graph. The Oximetry Report is used primarily for data summary and overview purposes.

P

Term	Definition
parameter	A value or setting.
patient data	Patient information. To begin entering patient information to be associated with a saved recording, the Patient History File appears. If you want to enter new patient information to be associated with a downloaded data set, select the New button on the Patient History File. The Save Data Set to File dialog box allows patient data to be entered.
patient history file	The Patient History File, located under the Edit pull-down menu, serves as a "starting point" for downloading patient data. It is used to store and update entered patient information. The Patient History File recalls the patient information to be associated with a new data file so that the user does not have to re-enter it. **NOTE:** Six example case studies are placed in the "DataSets" directory and the Patient History File as part of the initial installation of nVISION. Patient history information can be seen on any of nVISION's reports between the two black lines at the top of the reports.
patient ID	An identification number used to sort the Patient History File. The Patient ID field accepts up to 12 characters (alphabetic and numeric, as well as some special characters). This number can be any user-defined number, or it can be left blank if desired.

Term	Definition
patient information (patient info)	The Patient Info selection in the Edit pull-down menu brings up the Edit Patient Information dialog box, which allows users to store case-specific data without changing the entire patient history file. • When Update is selected, the patient information is updated and the dialog box closes. • When Cancel is selected, any changes made will be lost and the dialog box closes. **NOTE:** When patient information is updated in the Edit Patient Information dialog box, those updates will only be reflected in the currently open recording or report. This allows nVISION users to track and record patient changes without changing the patient history file.  Tip **NOTE:** If you need to delete text Comments fields, enter one space (press the Space bar one time) before clicking the Update button.
popup window	This window is a popup window–a Help window that opens when the underlined popup text is left-clicked once. The popup window closes when the mouse is left-clicked a second time. Popup windows are often used to define glossary terms.
percent drop for event (%)	A value that is set using the Analysis Parameters command. nVISION uses an SpO2 drop of 4% as the default setting for the Percent Drop For Event (%).
playback mode	A stage of operation where the oximeter will play back the patient data stored in memory.
print	All nVISION print functions use a standard Windows Print dialog box.
print preview	When Print Preview is selected, the report is displayed on screen as it would appear when printed. This option is available in the File pull-down menu.
print setup	When Print Setup is selected from the File pull-down menu, the standard Windows dialog box for print setup will appear.
progress bar	The progress bar shows the download progress for the recording currently being captured.
pulse	Rhythmic dilation of an artery through the contraction of the heart.
pulse event	Defined by values set using the Analysis Parameters command. Both Rate Change for Event (bpm) and Minimum Event Duration (sec) criteria must be met. In addition to the user-defined criteria, a downward trend must drop below 60 BPM or an upward trend must exceed 100 BPM to be classified as an event.
pulse rate	Heart rate
pulse rate graph enabled	A check box in the Display Parameters dialog box. Checking this box allows you to display pulse rate data in the Strip Chart and Full Study Reports.
pulse rate parameters	Values that are set using the Analysis Parameters command under the Options pull-down menu.

R

Term	Definition
radio button	A radio button is a control or switch used to select between two or more options in a dialog box.
rate change for event (BPM)	The rate change for an event is one of the user-defined parameters used as criteria for a pulse rate event.

Term	Definition
recording date	The date at which the data was recorded. The file name for storing the data set is generated from the name, recording date, and recording time. If you wish to change the name at any time, you may use the “Save As” option.
recording time	The time at which the data was recorded. The file name for storing the data set is generated from the name, recording date, and recording time. If you wish to change the name at any time, you may use the “Save As” option.
report	Options available from the Report pull-down menu are as follows: Oximetry Report, Strip Chart Report, Full Study Report, Respiration Rate Report, Summary Report, 6 Minute Walk Report, and Report Title. Each report contains distinct information. The currently selected report type is indicated with a checkmark to the left of the report in this menu. The default report type is Strip Chart Report when a data set is opened.
report menu	See Report Menu Commands.
report title	The title that is automatically applied to a report. The report title is often the name of a hospital or medical facility. Report titles can be changed by selecting Report Title from the Report pull-down menu.
respiration rate	Respiration rate is calculated as breaths per minute; i.e., 60 seconds divided by the interval (in seconds) since the last breath. This measurement is a breath-by-breath averaging, to respond quickly to changes in patient status. Essentially, respiration rate is the time interval since the previous breath occurred.
respiration rate graph enabled	A check box on the Display Parameters dialog box. Checking this box allows you to graphically display respiration data, when it is available.
respiration rate report	When you select the Respiration Rate Report option from the Report pull-down menu, the Respiration Rate Report is drawn in the main view for the currently open data set. The vertical scroll bars can be used to examine the report data. The Respiration Rate Report is only available when respiration data has been captured and downloaded.
respiratory pause	A respiratory pause is a time between breaths that is longer than that set by criteria using the Analysis Parameters command.
respiratory pause parameters	A value that is set using the Analysis Parameters command under the Options pull-down menu.
right-click	Click using the right mouse button.

S

Term	Definition
saturation criteria	The Analysis Parameters command under the Options pull-down menu allows you to select the percentage drop in saturation criteria over which the saturation must continue dropping in order to be considered an event.
save	Save the file. When the Save command is selected from the File pull-down menu, the opened case and any changes made to the case are saved to disk.
save data as	The Save As command allows you to save any data set with a different file name. For example, you may choose to perform some specific data analysis on an existing data set but not want to modify or overwrite results from a previous analysis. The Save As command allows you to perform modifications to existing data sets and save them with different file names while maintaining the original data sets.

Term	Definition
save data set to file	When you select a patient and choose OK, the Save Data Set To File dialog box appears with information about the selected patient appearing in the dialog box. This dialog box appears after downloading data from a pulse oximeter, and should not be confused with the Save As command.
save XML data	This command will cause the Oximetry Report data to be saved in an XML file with the same name as the .nmi file the study is saved in. Two other files in a .png format will be saved with the same name plus SpO2 or Pulse added to the name. These are the SpO2 and Pulse graphs which are referenced in the XML file. All three files must remain in the same directory to display properly. This can be opened in Microsoft Internet Explorer or any other XML utility. The Save XML Data command will be grayed out on all reports except the Oximetry Report. Once the XML files have been saved, they cannot be saved again until the study has been reopened with the Open Saved Data option in the File menu.
search criteria	A selection found in the Patient History dialog box. You can choose to search and list the patients by Last Name or Patient ID.
select recordings	When all data sets have been downloaded, the Select Recordings dialog box is shown. The user must highlight the recording to be saved and click on Save.
serial cable	Nonin Pulse Works with Serial Cable Oximeter 2120 UNI-RS232 2500, 2500A 1000MC or 1000RTC 3100 1000SC-WO 3150 Bluetooth wireless 4000 UNI-RS232 8500M 1000MC or 1000RTC 8600M 1000PFC 8600FOM 1000PFC 9600, 9700 UNI-RS232 9843, 9845, 9847 1000MC or 1000RTC
sleep screening (sleep study)	Also known as “sleep study.” An examination of sleeping patterns and data. The key sleep study statistic, called the “index,” is calculated as events per hour. Summary statistics for events are total number of events, cumulative time spent in events, average event duration, raw index value and the adjusted index where artifact and excluded data are not used. **NOTE:** Do not use nVISION data as the sole basis for making a medical diagnosis!
SpO2	A measure of arterial hemoglobin percent oxygen saturation.
SpO2 enabled	A check box on the Display Parameters dialog box. Checking this box displays SpO2 data on the Strip Chart and Full Study Reports.
SpO2 events	Events that are marked by SpO2 dropping a user-specified number of percentage points—and maintaining that drop for longer than the user-specified number of seconds criteria.
%SpO2 level	A parameter found on the Oximetry Report where the number of events occurring at each SpO2 level is shown.
SpO2 parameters	Values that are set using the Analysis Parameters command under the Options pull-down menu.
spreadsheet program	An alternative data analysis program.
strip chart characteristics	A group of parameters in the Display Parameters dialog box.

Term	Definition
strip chart report	The Strip Chart Report is the default report that appears when a data set is opened in nVISION software. The Strip Chart Report, which is displayed on the screen horizontally, provides a detailed graphical representation of SpO2, pulse rate, and respiration data (when applicable), where time is indicated on the x-axis of each graph. Events are calculated according to selected analysis parameters and are indicated with black marks above the data in each respective graph.
summarize	A function used with the rectangle and Strip Chart Report to investigate data and display summary statistics.
summarize data	A function used with the rectangle and Strip Chart Report to investigate data and display summary statistics.
summary statistics	The Summary Statistics text box appears by choosing the Summarize Data command from the Edit pull-down menu or clicking the tool bar icon after marking data on the Strip Chart report with a rectangle. Statistics listed include the Time interval of the data enclosed by the rectangle; Average, Minimum and Maximum numbers for collected data categories, as well as Number of Events per data category.

T

Term	Definition
time in events (min)	The sum of time durations for all events. Time in events is also a statistic on the Oximetry report.
time interval (HH:MM)	The Time Interval can be edited in the Display Parameters dialog box. All information must be displayed as HH:MM. To set a time interval, deselect "All Data," and then either manually enter a time interval or use the up and down arrows to select the desired interval.
time since last breath (sec)	The criteria for marking a Respiration Pause, which is set using the Analysis Parameters command. nVISION uses 30 seconds as the default setting for the Time Since Last Breath (Sec).
toolbar	The nVISION toolbar provides shortcuts to some frequently used commands.
total events	The total number of events during any measured time period.
tutorial	An example based on real data used for teaching or analysis.

U

Term	Definition
units of measure	A Radio Button control in the Report Title dialog box. Used for selecting the desired English or metric units (in/lb or cm/kg) for entering the height and weight in the Patient History File. (These units are displayed on reports.) **NOTE:** Before capturing (downloading) data for the first time, choose the Report Title command from the Report menu. A dialog box appears. Enter the report title (usually a hospital name). The dialog box also contains the Units of Measure radio button for in/lb or cm/kg. Select the desired English or metric units.

X

Term	Definition
XML options	See XML options.

FAQs (Frequently Asked Questions)

Working with Data Sets

System Requirements

What are the minimum system requirements?

- IBM-compatible PC with an 80486 or faster CPU
- Windows XP SP3, Windows Vista, Windows 7 (32 bit and 64 bit) or Windows 8 (32 bit and 64 bit) operating systems
- At least 256Mb of RAM (memory)
- At least 20Mb free space on the hard drive
- CD-ROM drive (24X speed or better)
- Video card with 800 x 600 VGA resolution
- At least 1 serial communications port

Downloading Data

What is the minimum amount of stored data that can be analyzed?

In order for data to be stored in the pulse oximeter's memory, the monitoring duration must be at least one minute.

If the download is not successful, will any error messages be displayed?

Yes, nVISION will prompt the user with error messages if the download is not successful.

After data is downloaded to a computer, is the data erased from the pulse oximeter's memory?

No, the data remains in the pulse oximeter's memory until it is erased, following the procedure to erase data stored in memory for the respective pulse oximeter.

At what point is data identified as an event?

An event is determined by user selected analysis parameters. In general, after both criteria are met or exceeded, the event occurs.

SpO2 data are also evaluated based on known patterns of desaturation occurrences during sleep. The data might not be marked as an event if the desaturation is gradual, for longer than two minutes in duration.

Pulse rate is evaluated based on trends recorded. The current value is compared to the previous value to see if both event criteria are met or exceeded. In addition, if the trend is upward, 100 must be exceeded; if the trend is downward, the pulse rate must drop below 60 BPM.

How is the Adjusted Index calculated?

Adjusted Index = Number of events / non-artifact time (hours)

What is Body-Mass Index and how is it calculated?

Body-mass index ("BMI") is a measurement of an individual's height-weight ratio. It is an individual's weight in kilograms divided by the square of that individual's height in meters.

Is data ever removed or deleted by nVISION?

Data is never removed or deleted. However if the pulse oximeter is not able to track an individual's blood oxygen saturation, pulse rate and/or respiration rate, a missing data marker is used for that sample interval. This unavailable or "missing" data will appear as a gap in the graphical representation of the patient's SpO2, pulse rate, or respiration rate. Depending upon the scale chosen for the report, the missing data may or may not be noticeable.

With what Windows software is nVISION not verified?

nVISION has not been verified with Windows® ME.

Using Reports

Can I change the report title?

Yes, the title of a specific patient report can easily be changed to customize your reports.

The report title can be modified when all saved data sets are closed. All data sets printed thereafter will contain the new report title.

Can I combine two or more data sets into one data set?

To merge two or more data sets, highlight the data sets you wish to merge in the Select Recordings dialog box, and then click Save. In the Strip Chart and Full Study reports, the merged recordings will be shown with a "gap" to identify that the data is not contiguous. The gap is indicated by crosshatched shading.

If the date and time are not set in the pulse oximeter before data is recorded, the gap between the merged recordings will default to 10 minutes.

NOTE: *When a 3100 or 3150 Wrist Oximeter is used, data sets that have been recorded with different sample rates cannot be merged. This means that when users select the first data set, only data sets that have the same sample rates may also be selected.*

How are excluded data identified on the reports?

On the Oximetry Report, excluded data is identified in the summary information listed as "% Artifact."

On all reports, the "Time Analyzed" has the excluded data removed. In short, Duration minus Time Analyzed = Excluded Data.

The excluded data time is also added to the missing data-so that the % Artifact is both the missing and excluded data.

Can I convert data to an ASCII format?

Yes, data can be exported from a data set. Exported data is saved in ASCII format, comma delimited. This may be helpful if interested in evaluating the data in an Excel spreadsheet for example.

Printing Data and Reports

Can I print on-screen data?

Yes, the Strip Chart report allows you to print on-screen data. The Oximetry Report is a one-page summary of a patient's entire monitoring session. Additionally, the Full Study Report prints all the data.

How do I print the current report?
How do I preview the current report on the screen as it will appear printed?
How do I select a printer and printer connection?
How do I program the 3100 or 3150 Wrist Oximeter?

Storing Data

Will nVISION "auto save" my open files?

No, any changes made to a file must be saved (using Save or Save As) before closing the file. If a file is closed without saving the changes, the changes will be lost.

When should I archive my patient files/data sets?

Archive and storage of patient records are important issues that will need to be addressed by the user. At a minimum, we recommend backing up all patient files—copying the files from the Nonin and Nonin\Data Sets directory on the PC's hard drive onto a network drive or another medium such as floppy disk or CD-Rom.

System Defaults

Can I change the system defaults for the analysis and display parameters?

Yes, nVISION features the ability to change the system defaults. The system analysis parameters and default parameters can be accessed if all data sets are closed.

NOTE: *After the system defaults are modified, all data sets collected thereafter will be analyzed based on the new parameters unless case-specific parameters changes are made.*

Customer Support

Contacting Customer Support

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NOTE: When calling Nonin Customer Support, you will be asked to provide the nVISION software key code, which is displayed in the About nVISION window, and is also printed on the nVISION CD-ROM jacket.

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Tlf.: +1 (763) 553-9968

E-mail: technicalservice@nonin.com

Protective Order

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

APPLE INC., Plaintiff, v. MASIMO CORPORATION and SOUND UNITED, LLC, Defendants.	C.A. No. 22-1377-MN-JLH **JURY TRIAL DEMANDED**
MASIMO CORPORATION, Counter-Claimant, v. APPLE INC., Counter-Defendant.	
APPLE INC., Plaintiff, v. MASIMO CORPORATION and SOUND UNITED, LLC, Defendants.	C.A. No. 22-1378-MN-JLH **JURY TRIAL DEMANDED**
MASIMO CORPORATION and CERCACOR LABORATORIES, INC., Counter-Claimants, v. APPLE INC., Counter-Defendant.	

AGREED PROTECTIVE ORDER
REGARDING THE DISCLOSURE AND USE OF DISCOVERY MATERIAL

Plaintiff and Counter-Defendant Apple Inc. ("Plaintiff"), Defendants and Counter-Claimants Masimo Corporation and Sound United, LLC and Counter-Claimant Cercacor Laboratories, Inc. (together, "Masimo") anticipate that documents, testimony, or information containing or reflecting confidential, proprietary, trade secret, and/or commercially sensitive information are likely to be disclosed or produced during the course of discovery, initial disclosures, and supplemental disclosures in these cases and request that the Court enter this Order setting forth the conditions for treating, obtaining, and using such information.

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the Court finds good cause for the following Agreed Protective Order Regarding the Disclosure and Use of Discovery Material ("Order" or "Protective Order").

1. **PURPOSES AND LIMITATIONS**

(a) Protected Material designated under the terms of this Protective Order shall be used by a Receiving Party solely for these cases, and shall not be used directly or indirectly for any other purpose whatsoever.

(b) The Parties acknowledge that this Order does not confer blanket protections on all disclosures during discovery, or in the course of making initial or supplemental disclosures under Rule 26(a). Designations under this Order shall be made with care and shall not be made absent a good faith belief that the designated material satisfies the criteria set forth below. If it comes to a Producing Party's attention that designated material does not qualify for protection at all, or does not qualify for the level of protection initially asserted, the Producing Party must promptly notify all other Parties that it is withdrawing or changing the designation.

(c) Other Proceedings. By entering this order and limiting the disclosure of information in these cases, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a request or motion that would require disclosure of another party's information designated "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," pursuant to this Order shall promptly notify that party of the request or motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

2. **DEFINITIONS**

(a) "Affiliate" means any corporation, company, or other business entity over which a Party has the power to direct or cause the direction of the management, policies, or legal actions through: (1) at least 50% ownership of voting securities; or (2) contract; or (3) other means.

(b) "Discovery Material" means all items or information, including from any non-party, regardless of the medium or manner generated, stored, or maintained (including, among other things, testimony, transcripts, or tangible things) that are produced, disclosed, or generated in connection with discovery or Rule 26(a) disclosures in these cases.

(c) "Outside Counsel" means (i) outside counsel who appear on the pleadings as counsel for a Party and (ii) partners, associates, and staff of such counsel to whom it is reasonably necessary to disclose the information for this litigation.

(d) "Patents-in-suit" means U.S. Patent Nos. D735,131, D883,279, D947,842, D962,936, 10,076,257, 10,627,783, 10,942,491, 10,987,054, 11,106,352, 11,474,483, 10,912,501, 10,912,502, 10,945,648, 10,687,743, 10,687,745, 10,722,159, 7,761,127, 8,190,223, 10,736,507,

and 10,984,911 and any other patent asserted in these cases, as well as any related patents, patent applications, provisional patent applications, continuations, and/or divisionals.

(e) "Party" means any party to these cases, including all of its officers, directors, employees, consultants, vendors, retained experts, and outside counsel and their support staffs.

(f) "Producing Party" means any Party or non-party that discloses or produces any Discovery Material in these cases.

(g) "Protected Material" means any Discovery Material that is designated as "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," as provided for in this Order. Protected Material shall not include: (i) advertising materials that have been actually published or publicly disseminated; and (ii) materials that show on their face they have been disseminated to the public.

(h) "Receiving Party" means any Party who receives Discovery Material from a Producing Party.

(i) "Source Code" means computer code, scripts, assembly, binaries, object code, source code listings (e.g., file names and path structure), descriptions of source code (e.g., descriptions of declarations, functions, and parameters), object code listings and descriptions of object code, Hardware Description Language (HDL) or Register Transfer Level (RTL) files that describe the hardware design of any ASIC or other chip, and native Computer Aided Design (CAD) files that describe the hardware design of any component, the disclosure of which to another Party or non-party is likely to cause harm or competitive disadvantage to the Producing Party. To avoid any doubt, still images of CAD files are not Source Code and will not be subject to the

disclosure and review restrictions in Section 11. Still images of CAD files may be designated as "CONFIDENTIAL" or "CONFIDENTIAL - ATTORNEYS' EYES ONLY," as provided for in this Order.

3. **COMPUTATION OF TIME**

The computation of any period of time prescribed or allowed by this Order shall be governed by the provisions for computing time set forth in Federal Rules of Civil Procedure 6.

4. **SCOPE**

(a) The protections conferred by this Order cover not only Discovery Material governed by this Order as addressed herein, but also any information copied or extracted therefrom, as well as all copies, excerpts, summaries, or compilations thereof, plus testimony, conversations, or presentations by Parties or their counsel in court or in other settings that might reveal Protected Material.

(b) Nothing in this Protective Order shall prevent or restrict a Producing Party's own disclosure or use of its own Protected Material for any purpose, and nothing in this Order shall preclude any Producing Party from showing its Protected Material to an individual who prepared the Protected Material.

(c) Nothing in this Order shall be construed to prejudice any Party's right to use any Protected Material with the consent of the Producing Party or by order of the Court.

(d) This Order is without prejudice to the right of any Party to seek further or additional protection of any Discovery Material or to modify this Order in any way, including, without limitation, an order that certain matter not be produced at all.

(e) Any use of Protected Material at trial shall be governed by the orders of the trial judge and other applicable authorities. This Order does not govern the use of Protected Material at trial.

5. **DURATION**

Even after the termination of these cases, the confidentiality obligations imposed by this Order shall remain in effect until a Producing Party agrees otherwise in writing or a court order otherwise directs.

6. **ACCESS TO AND USE OF PROTECTED MATERIAL**

(a) Basic Principles. All Protected Material shall be used solely for these cases or any related appellate proceedings, and not for any other purpose whatsoever, including without limitation, any other litigation, patent prosecution or acquisition, patent reexamination or reissue proceedings, or any business or competitive purpose or function. Protected Material shall not be distributed, disclosed, or made available to anyone except as expressly provided in this Order.

(b) Patent Prosecution Bar. After the adoption of this provision by the parties, Outside Counsel and any person associated with a Party who receives a Producing Party's material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order or who has access to, accesses, or otherwise learns of, in whole or in part, said material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order shall not prepare, prosecute, supervise, advise, counsel, or assist in the preparation or prosecution of any patent application seeking a patent on behalf of the Receiving Party or its acquirer, successor, predecessor, or Affiliate in the field of non-invasive monitoring and/or consumer wearables (generally or as

described in any patent in suit) during the pendency of this Action and for two years after final termination of this action, including all appeals. To avoid any doubt, "prosecution" as used in this section does not include representing or advising a Party before a domestic or foreign agency in connection with a reissue, ex parte reexamination, covered business method review, inter partes review, opposition, cancelation, or similar proceeding; though in connection with any such foreign or domestic agency proceeding involving the patents-in-suit, any attorney who has access to, accesses, obtains, receives, or otherwise learns, in whole or in part, any other Party's "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" shall not: (i) participate in the preparation, prosecution, supervision, advice, counsel, or assistance of any amended claims; (ii) reveal a Producing Party's Protected Material to any prosecuting reexamination counsel or agent; or (iii) use a Producing Party's Protected Material for any purpose not permitted by Section 1.

(c) Secure Storage, No Export. Protected Material must be stored and maintained by a Receiving Party at a location in the United States and in a secure manner that ensures that access is limited to the persons authorized under this Order. To ensure compliance with applicable United States Export Administration Regulations, Protected Material may not be exported outside the United States or released to any foreign national, even if within the United States. This applies to such information regardless of whether it is in the form of a stand-alone document or as an exhibit, attachment, or appendix to anything, including but not limited to briefs, reports, letters to counsel, discovery responses, or court filings—whether drafts or final versions. Foreign nationals shall not include the Parties' Outside Counsel who reside in the United States, agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A, and who are identified in writing to the Producing Party. However, the Parties' Outside Counsel

may access briefs, reports, letters to counsel, discovery responses, and court filings (including drafts) that contain Protected Material for purposes of working on these cases while traveling temporarily outside the United States, exclusive of any exhibits or appendices that attach or substantially reproduce or summarize documents, data, or testimony that have been designated by any other party as Protected Material. The Parties will use their best efforts to minimize the amount of Protected Materials in those documents (including without limitation by redacting references to Protected Materials that are not necessary for the work performed outside of the United States) to help ensure the security of the Parties' Protected Materials. Also, if this case eventually requires depositions or experts located outside the United States, the parties will revisit this issue and attempt to agree about exporting specific materials to the extent necessary. The Parties agree that neither Party waives the right to seek amendment of this Protective Order by the Court, following a meet and confer, if other circumstances concerning exportation arise in this case.

(d) Legal Advice Based on Protected Material. Nothing in this Protective Order shall be construed to prevent counsel from advising their clients with respect to these cases based in whole or in part upon Protected Materials, provided counsel does not disclose the Protected Material itself except as provided in this Order.

(e) Limitations. Nothing in this Order shall restrict in any way a Producing Party's use or disclosure of its own Protected Material. Nothing in this Order shall restrict in any way the use or disclosure of Discovery Material by a Receiving Party: (i) that is or has become publicly known through no fault of the Receiving Party; (ii) that is lawfully acquired by or known to the Receiving Party independent of the Producing Party; (iii) previously produced, disclosed and/or provided by the Producing Party to the Receiving Party or a non-party without an

obligation of confidentiality and not by inadvertence or mistake; (iv) with the consent of the Producing Party; or (v) pursuant to order of the Court.

7. **DESIGNATING PROTECTED MATERIAL**

(a) Available Designations. Any Producing Party may designate Discovery Material with any of the following designations, provided that it meets the requirements for such designations as provided for herein: "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE."

(b) Written Discovery and Documents and Tangible Things. Written discovery, documents (which include "electronically stored information," as that phrase is used in Federal Rule of Procedure 34), and tangible things that meet the requirements for the confidentiality designations listed in Section 7(a) may be so designated by placing the appropriate designation on every page of the written material prior to production. For digital files being produced, the Producing Party may mark each viewable page or image with the appropriate designation, and mark the medium, container, and/or communication in which the digital files were contained. In the event that original documents are produced for inspection, the original documents shall be presumed "CONFIDENTIAL – ATTORNEYS' EYES ONLY" during the inspection and re-designated, as appropriate during the copying process.

(c) Native Files. Where electronic files and documents are produced in native electronic format, such electronic files and documents shall be designated for protection under this Order by appending to the file names or designators information indicating whether the file contains "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," material, or

shall use any other reasonable method for so designating Protected Materials produced in electronic format. When electronic files or documents are printed for use at deposition, in a court proceeding, or for provision in printed form to an expert or consultant pre-approved pursuant to Section 12, the party printing the electronic files or documents shall affix a legend to the printed document corresponding to the designation of the Producing Party and including the production number and designation associated with the native file. The parties reserve the right to object to the use of any image format version of a document produced in native format to the extent any information has been altered.

(d) Depositions and Testimony. Parties or testifying persons or entities may designate depositions and other testimony with the appropriate designation by indicating on the record at the time the testimony is given or by sending written notice of how portions of the transcript of the testimony are designated within fifteen (15) days of receipt of the transcript of the testimony. If no indication on the record is made, all information disclosed during a deposition shall be deemed "CONFIDENTIAL – ATTORNEYS' EYES ONLY" until the time within which it may be appropriately designated as provided for herein has passed. Any Protected Material that is used in the taking of a deposition shall remain subject to the provisions of this Protective Order, along with the transcript pages of the deposition testimony dealing with such Protected Material. In such cases the court reporter shall be informed of this Protective Order and shall be required to operate in a manner consistent with this Protective Order. In the event the deposition is videotaped, the original and all copies of the videotape shall be marked by the video technician to indicate that the contents of the videotape are subject to this Protective Order, substantially along the lines of "This videotape contains confidential testimony used in this case and is not to be viewed or the contents thereof to be displayed or revealed except pursuant to the terms of the operative

Protective Order in this matter or pursuant to written stipulation of the parties." Counsel for any Producing Party shall have the right to exclude from oral depositions, other than the deponent, deponent's counsel, the reporter and videographer (if any), any person who is not authorized by this Protective Order to receive or access Protected Material based on the designation of such Protected Material. Such right of exclusion shall be applicable only during periods of examination or testimony regarding such Protected Material.

8. **DISCOVERY MATERIAL DESIGNATED AS "CONFIDENTIAL"**

(a) A Producing Party may designate Discovery Material as "CONFIDENTIAL" if it contains or reflects confidential, proprietary, and/or commercially sensitive information.

(b) Unless otherwise ordered by the Court, Discovery Material designated as "CONFIDENTIAL" may be disclosed only to the following:

(i) The Receiving Party's Outside Counsel, such counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Officers or employees of the Receiving Party, who may be, but need not be, in-house counsel for the Receiving Party, as well as their immediate paralegals and staff, to whom disclosure is reasonably necessary for this case, provided that each such person has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(iii) Any outside expert or consultant retained by the Receiving Party to assist in these cases, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current

officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (d) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iv) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is an employee of the Producing Party, or identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from metadata, cover emails, or other records of distribution) that the witness has seen or had access to the document previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(v) Court reporters, stenographers and videographers retained to record testimony taken in these cases, and their staff;

(vi) The Court, jury, and court personnel;

(vii) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(viii) Mock jurors having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A.

(ix) Any mediator who is assigned to hear these matters, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(x) Any other person with the prior written consent of the Producing Party.

9. **DISCOVERY MATERIAL DESIGNATED AS "CONFIDENTIAL – ATTORNEYS' EYES ONLY"**

(a) A Producing Party may designate Discovery Material as "CONFIDENTIAL – ATTORNEYS' EYES ONLY" if it contains or reflects information that is extremely confidential and/or sensitive in nature and the Producing Party reasonably believes that the disclosure of such Discovery Material is likely to cause harm or significant competitive disadvantage to the Producing Party. The Parties agree that the following information, if non-public, shall be presumed to merit the "CONFIDENTIAL – ATTORNEYS' EYES ONLY" designation: trade secrets, pricing information, financial data, sales information, sales or marketing forecasts or plans, business plans, sales or marketing strategy, product development information, engineering documents, testing documents, employee information, and other non-public information of similar competitive and business sensitivity.

(b) Unless otherwise ordered by the Court, Discovery Material designated as "CONFIDENTIAL – ATTORNEYS' EYES ONLY" may be disclosed only to:

(i) The Receiving Party's Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such

Outside Counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director, or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from testimony, metadata, cover emails, or other records of distribution) that the witness has previously seen or had access to the document or the information contained therein; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that

the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(vii) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(viii) Any other person with the prior written consent of the Producing Party.

(c) In addition, a Party may disclose arguments and materials derived from Discovery Material designated as "CONFIDENTIAL – ATTORNEYS' EYES ONLY" to mock jurors who have signed an undertaking or agreement agreeing not to publicly disclose Protected Material and to keep any information concerning Protected Material confidential. A Party may not disclose to mock jurors any original, as-produced materials or information (including, for example, documents, deposition testimony, or interrogatory responses) produced by another Party designated as "CONFIDENTIAL - ATTORNEYS' EYES ONLY."

10. **DISCOVERY MATERIAL DESIGNATED AS "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE"**

(a) To the extent production of Source Code becomes necessary to the prosecution or defense of the cases, a Producing Party may designate Source Code as

"CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" if it comprises or includes confidential, proprietary, and/or trade secret Source Code.

(b) Nothing in this Order shall be construed as a representation or admission that Source Code is properly discoverable in these cases, or to obligate any Party to produce any Source Code.

(c) Unless otherwise ordered by the Court, Discovery Material designated as "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" shall be subject to the provisions set forth in Section 11 below, and may be disclosed, subject to Section 11 below, solely to:

(i) The Receiving Party's Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such Outside Counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not

transport them to or access them from any foreign jurisdiction; and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the material as an author, addressee, or recipient of the material, or if there are indicia (such as from testimony, metadata, emails, or other records of distribution) that the witness has seen or had access to the materials previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(vii) Any other person with the prior written consent of the Producing Party.

11. **DISCLOSURE AND REVIEW OF SOURCE CODE**

(a) Any Source Code that is produced by Plaintiff will be made available for inspection at the San Francisco office of its outside counsel, Desmarais LLP, or any other location mutually agreed by the Parties. Any Source Code that is produced by Masimo will be made

available for inspection at the Orange County office of their outside counsel, Knobbe Martens Olsen & Bear LLP, or any other location mutually agreed by the Parties. Source Code will be made available for inspection between the hours of 8 a.m. and 6 p.m. on business days (i.e., weekdays that are not Federal holidays), although the Parties will be reasonable in accommodating reasonable requests to conduct inspections at other times.

(b) Prior to the first inspection of any requested Source Code, the Receiving Party shall provide ten (10) days' notice of its intent to review the Source Code that has been made available by the Producing Party and, if known, the specific Source Code the Receiving Party intends to inspect. The Receiving Party shall provide seven (7) days' notice prior to any additional inspections.

(c) Source Code that is designated "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" shall be produced for inspection and review subject to the following provisions, unless otherwise agreed by the Producing Party:

(i) All Source Code shall be made available by the Producing Party to the Receiving Party's Outside Counsel and/or experts in a secure room on a secured computer without Internet access or network access to other computers and on which all access ports have been disabled (except for one printer port), as necessary and appropriate to prevent and protect against any unauthorized copying, transmission, removal or other transfer of any Source Code outside or away from the computer on which the Source Code is provided for inspection (the "Source Code Computer" in the "Source Code Review Room"). The Producing Party shall install tools that are sufficient for viewing and searching the code produced, on the platform produced, if such tools exist and are presently used in the ordinary course of the Producing Party's business. The Receiving Party's Outside Counsel and/or experts may request that commercially available

software tools for viewing and searching Source Code be installed on the secured computer, provided, however, that (a) the Receiving Party possesses an appropriate license to such software tools; (b) the Producing Party approves such software tools (approvals will not be unreasonably denied); and (c) such other software tools are reasonably necessary for the Receiving Party to perform its review of the Source Code consistent with all of the protections herein. The Receiving Party must provide the Producing Party with the CD or DVD or other media containing such licensed software tool(s) at least seven (7) days in advance of the date upon which the Receiving Party wishes to have the additional software tools available for use on the Source Code Computer.

(ii) No recordable media or recordable devices, including without limitation sound recorders, computers, cellular telephones, peripheral equipment, cameras, CDs, DVDs, or drives of any kind, shall be permitted into the Source Code Review Room.

(iii) The Receiving Party's Outside Counsel and/or experts shall be entitled to take notes relating to the Source Code but may not copy the Source Code into the notes and may not take such notes electronically on the Source Code Computer itself or any other computer.

(iv) The Producing Party may visually monitor the activities of the Receiving Party's representatives during any Source Code review, but only to ensure that no unauthorized electronic records of the Source Code and no information concerning the Source Code are being created or transmitted in any way.

(v) No copies of all or any portion of the Source Code may leave the room in which the Source Code is inspected except as otherwise provided herein. Further, no other written or electronic record of the Source Code is permitted except as otherwise provided herein. The Producing Party shall make available a laser printer with commercially reasonable

printing speeds for on-site printing during inspection of the Source Code. The Receiving Party may print limited portions of the Source Code only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). The Receiving Party may print the Source Code in 12-point font and with information necessary to later identify that Source Code, such as, but not limited to, a header or footer, that identifies the file name and directory path. Any printed portion that consists of more than fifteen (15) pages of a continuous block of Source Code shall be presumed to be excessive, and the burden shall be on the Receiving Party to demonstrate the need for such a printed copy. The Receiving Party may print out no more than 200 pages total without prior agreement from the Producing Party or order of the Court. The Receiving Party shall not print Source Code in order to review blocks of Source Code elsewhere in the first instance, i.e., as an alternative to reviewing that Source Code electronically on the Source Code Computer, as the Parties acknowledge and agree that the purpose of the protections herein would be frustrated by printing portions of code for review and analysis elsewhere, and that printing is permitted only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). Upon printing any such portions of Source Code, the printed pages shall be collected by the Producing Party. The Producing Party shall Bates number, copy, and label "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" any pages printed by the Receiving Party. Within seven (7) days, the Producing Party shall either (i) provide one copy set of such pages to the Receiving Party or (ii) inform the Requesting Party that it objects that the printed portions are excessive and/or not done for a permitted purpose. If, after meeting and conferring, the Producing Party and the Receiving Party cannot resolve the objection, the Receiving Party shall be entitled to seek a Court resolution of whether the printed Source Code in question is narrowly tailored and was printed for a permitted purpose. The

burden shall be on the Receiving Party to demonstrate that such printed portions are no more than is reasonably necessary for a permitted purpose and not merely printed for the purposes of review and analysis elsewhere. The printed pages shall constitute part of the Source Code produced by the Producing Party in these cases.

(vi) All persons who will review a Producing Party's Source Code on behalf of a Receiving Party, including members of a Receiving Party's outside law firm, shall be identified in writing to the Producing Party at least five (5) days in advance of the first time that such person reviews such Source Code. Such identification shall be in addition to any other disclosure required under this Order. All persons viewing Source Code shall sign on each day they view Source Code a log that will include the names of persons who enter the locked room to view the Source Code and when they enter and depart. The Producing Party shall be entitled to a copy of the log upon one (1) day's advance notice to the Receiving Party.

(vii) Unless otherwise agreed in advance by the Parties in writing, following each day on which inspection is done under this Order, the Receiving Party's Outside Counsel and/or experts shall remove all notes, documents, and all other materials from the Source Code Review Room. The Producing Party shall not be responsible for any items left in the room following each inspection session, and the Receiving Party shall have no expectation of confidentiality for any items left in the room following each inspection session without a prior agreement to that effect. Proper identification of all authorized persons shall be provided prior to any access to the secure room or the computer containing Source Code. Proper identification requires showing, at a minimum, a photo identification card sanctioned by the government of any State of the United States, by the government of the United States, or by the nation state of the authorized person's current citizenship. Access to the secure room or the Source Code Computer

may be denied, at the discretion of the supplier, to any individual who fails to provide proper identification.

(viii) Other than as provided above, the Receiving Party will not copy, remove, or otherwise transfer any Source Code from the Source Code Computer including, without limitation, copying, removing, or transferring the Source Code onto any recordable media or recordable device. The Receiving Party will not transmit any Source Code in any way from the Producing Party's facilities or the offices of its Outside Counsel of record.

(ix) The Receiving Party's Outside Counsel of record may make no more than three (3) additional paper copies of any portions of the Source Code received from a Producing Party pursuant to Section 11(c)(v), not including copies attached to court filings or used at depositions, and shall maintain a log of all paper copies of the Source Code. The log shall include the names of the reviewers and/or recipients of paper copies and locations where the paper copies are stored. Upon one (1) day's advance notice to the Receiving Party by the Producing Party, the Receiving Party shall provide a copy of this log to the Producing Party.

(x) The Receiving Party's Outside Counsel of record and any person receiving a copy of any Source Code shall maintain and store any paper copies of the Source Code at their offices in a manner that prevents duplication of or unauthorized access to the Source Code, including, without limitation, storing the Source Code in a locked room or cabinet at all times when it is not in use. No more than a total of fifteen (15) individuals identified by the Receiving Party shall have access to the printed portions of Source Code (except insofar as such code appears in any court filing or expert report).

(xi) For depositions, the Receiving Party shall not bring copies of any printed Source Code. Rather, at least seven (7) days before the date of the deposition, the Receiving

Party shall notify the Producing Party about the specific portions of Source Code it wishes to use at the deposition, and the Producing Party shall bring printed copies of those portions to the deposition for use by the Receiving Party. The Producing Party shall also accommodate reasonable requests from the Receiving Party to make a Source Code Computer available at the deposition for use at the deposition. Copies of Source Code that are marked as deposition exhibits shall not be provided to the Court Reporter or attached to deposition transcripts; rather, the deposition record will identify the exhibit by its production numbers. All paper copies of Source Code brought to the deposition shall remain with the Producing Counsel's Outside Counsel for secure destruction in a timely manner following the deposition.

(xii) Except as provided in this section, absent express written permission from the Producing Party, the Receiving Party may not create electronic images, or any other images, or make electronic copies, of the Source Code from any paper copy of Source Code for use in any manner (including by way of example only, the Receiving Party may not scan the Source Code to a PDF or photograph the code). Images or copies of Source Code shall not be included in correspondence between the Parties (references to production numbers shall be used instead), and shall be omitted from pleadings and other papers whenever possible. If a Party reasonably believes that it needs to submit a portion of Source Code as part of a filing with the Court, the Parties shall meet and confer as to how to make such a filing while protecting the confidentiality of the Source Code and such Source Code will not be filed absent agreement from the Producing Party that the confidentiality protections will be adequate. If a Producing Party agrees to produce an electronic copy of all or any portion of its Source Code or provide written permission to the Receiving Party that an electronic or any other copy needs to be made for a Court filing, access to the Receiving Party's submission, communication, and/or disclosure of electronic files or other materials

containing any portion of Source Code (paper or electronic) shall at all times be limited solely to individuals who are expressly authorized to view Source Code under the provisions of this Order. Where the Producing Party has provided the express written permission required under this provision for a Receiving Party to create electronic copies of Source Code, the Receiving Party shall maintain a log of all such electronic copies of any portion of Source Code in its possession or in the possession of its retained consultants, including the names of the reviewers and/or recipients of any such electronic copies, and the locations and manner in which the electronic copies are stored. Additionally, any such electronic copies must be labeled "CONFIDENTIAL - ATTORNEYS' EYES ONLY - SOURCE CODE" as provided for in this Order.

12. **NOTICE OF DISCLOSURE**

(a) Prior to disclosing any Protected Material to any person described in Sections 8(b)(iii), 9(b)(ii), or 10(c)(ii) (referenced below as "Person"), the Party seeking to disclose such information shall provide the Producing Party with written notice that includes:

(i) the name of the Person;

(ii) an up-to-date curriculum vitae of the Person;

(iii) the present employer and title of the Person;

(iv) an identification of all of the Person's past and current employment and consulting relationships in the past five years, including direct relationships and relationships through entities owned or controlled by the Person, including but not limited to an identification of any individual or entity with or for whom the person is employed or to whom the person provides consulting services relating to the design, development, operation, or patenting of technologies relating to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit), or relating to the acquisition of intellectual property assets relating

to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit);

(v) an identification of all pending patent applications on which the Person is named as an inventor, in which the Person has any ownership interest, or as to which the Person has had or anticipates in the future any involvement in advising on, consulting on, preparing, prosecuting, drafting, editing, amending, or otherwise affecting the scope of the claims; and

(vi) a list of the cases in which the Person has testified at deposition or trial within the last five (5) years.

Further, the Party seeking to disclose Protected Material shall provide such other information regarding the Person's professional activities reasonably requested by the Producing Party for it to evaluate whether good cause exists to object to the disclosure of Protected Material to the outside expert or consultant.

(b) Within ten (10) days of receipt of the disclosure of the Person, the Producing Party or Parties may object in writing to the Person for good cause. In the absence of an objection at the end of the ten (10) day period, the Person shall be deemed approved under this Protective Order. There shall be no disclosure of Protected Material to the Person prior to expiration of this ten (10) day period. If the Producing Party objects to disclosure to the Person within such ten (10) day period, the Parties shall meet and confer via telephone or in person within four (4) days following the objection and attempt in good faith to resolve the dispute on an informal basis. If the dispute is not resolved, the Party objecting to the disclosure will have four (4) days from the date of the meet and confer to seek relief from the Court and shall have the burden of proving the need for a protective order. If relief is not sought from the Court within that time, the objection

shall be deemed withdrawn. If relief is sought, designated materials shall not be disclosed to the Person in question until the Court resolves the objection.

(c) For purposes of this section, "good cause" shall include an objectively reasonable concern that the Person will, advertently or inadvertently, use or disclose Discovery Material in a way or ways that are inconsistent with the provisions contained in this Order.

(d) Prior to receiving any Protected Material under this Order, the Person must execute a copy of the "Agreement to Be Bound by Protective Order" (Exhibit A hereto) and serve it on all Parties.

(e) An initial failure to object to a Person under this Section 12 shall not preclude the nonobjecting Party from later objecting to continued access by that Person for good cause. If an objection is made, the Parties shall meet and confer via telephone or in person within seven (7) days following the objection and attempt in good faith to resolve the dispute informally. If the dispute is not resolved, the Party objecting to the disclosure will have seven (7) days from the date of the meet and confer to seek relief from the Court. The designated Person may continue to have access to information that was provided to such Person prior to the date of the objection. If a later objection is made, no further Protected Material shall be disclosed to the Person until the Court resolves the matter or the Producing Party withdraws its objection. Notwithstanding the foregoing, if the Producing Party fails to move for a protective order within seven (7) business days after the meet and confer, further Protected Material may thereafter be provided to the Person.

13. **CHALLENGING DESIGNATIONS OF PROTECTED MATERIAL**

(a) A Party shall not be obligated to challenge the propriety of any designation of Discovery Material under this Order at the time the designation is made, and a failure to do so shall not preclude a subsequent challenge thereto.

(b) Any challenge to a designation of Discovery Material under this Order shall be written, shall be served on Outside Counsel for the Producing Party, shall particularly identify the documents or information that the Receiving Party contends should be differently designated, and shall state the grounds for the objection. Thereafter, further protection of such material shall be resolved in accordance with the following procedures:

(i) The objecting Party shall have the burden of conferring either in person, in writing, or by telephone with the Producing Party claiming protection (as well as any other interested party) in a good faith effort to resolve the dispute. The Producing Party shall have the burden of justifying the disputed designation;

(ii) Failing agreement, the Receiving Party may bring a request or motion to the Court for a ruling that the Discovery Material in question is not entitled to the status and protection of the Producing Party's designation. The Parties' entry into this Order shall not preclude or prejudice either Party from arguing for or against any designation, establish any presumption that a particular designation is valid, or alter the burden of proof that would otherwise apply in a dispute over discovery or disclosure of information;

(iii) Notwithstanding any challenge to a designation, the Discovery Material in question shall continue to be treated as designated under this Order until one of the following occurs: (a) the Party who designated the Discovery Material in question withdraws such designation in writing; or (b) the Court rules that the Discovery Material in question is not entitled to the designation.

14. **DATA SECURITY**

(a) The Receiving Party shall implement an information security management system ("ISMS") to safeguard Protected Materials, including reasonable and appropriate

administrative, physical, and technical safeguards, and network security and encryption technologies governed by written policies and procedures, which shall comply with at least one of the following standards: (a) the International Organization for Standardization's 27001 standard; (b) the National Institute of Standards and Technology's (NIST) 800-53 standard; (c) the Center for Internet Security's Critical Security Controls, Version 8; or (d) the most recently published version of another widely recognized industry or government cybersecurity framework. The Parties shall implement encryption of all Protected Materials in transit outside of network(s) covered by the Party's ISMS (and at rest, where reasonably practical). Moreover, the Parties agree not to access Protected Materials from public computers.

(b) If the Receiving Party becomes aware of any unauthorized access, use, or disclosure of Protected Materials or devices containing Protected Materials ("Data Breach"), the Receiving Party shall promptly, and in no case later than 48 hours after learning of the Data Breach, notify the Producing Party in writing and fully cooperate with the Producing Party as may be reasonably necessary to (a) determine the source, extent, or methodology of such Data Breach, (b) recover or protect Protected Materials, and/or (c) to satisfy the Producing Party's legal, contractual, or other obligations. For the avoidance of doubt, notification obligations under this section arise when the Receiving Party both (a) learns of a Data Breach, and (b) learns that any of the Producing Party's Protected Materials are potentially subject to the Data Breach. The notification obligations set forth in this section do not run from the time the Data Breach itself.

(c) If the Receiving Party is aware of a Data Breach, the Parties shall meet and confer in good faith regarding any adjustments that should be made to the discovery process and discovery schedule in these cases, potentially including but not limited to (1) additional security measures to protect Discovery Material; (2) a stay or extension of discovery pending investigation

of a Data Breach and/or implementation of additional security measures; and (3) a sworn assurance that Discovery Material will be handled in the future only by entities not impacted by the Data Breach. In the event of a Data Breach affecting Protected Material of the Designating Party, at the Designating Party's request, the Receiving Party within 10 business days shall provide a copy of its most recent ISMS policies and procedures that relate to the safeguarding of Protected Materials and that preceded the Data Breach. Further, the Receiving Party shall submit to reasonable discovery concerning the Data Breach.

15. **SUBPOENAS OR COURT ORDERS**

(a) If at any time Protected Material is subpoenaed by any court, arbitral, administrative, or legislative body, the Party to whom the subpoena or other request is directed shall immediately give prompt written notice thereof to every Party who has produced such Discovery Material and to its counsel and shall provide each such Party with an opportunity to move for a protective order regarding the production of Protected Materials implicated by the subpoena. The Producing Party must also notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order, and include a copy of this Protective Order. The parties agree to work together to allow the Producing Party to seek a protective order, after the filing of which the Party served with the subpoena or court order shall not produce any information designated in this action as "CONFIDENTIAL – ATTORNEYS EYES ONLY" or "CONFIDENTIAL – ATTORNEYS EYES ONLY – SOURCE CODE" before a determination on the protective order by the court from which the subpoena or order issued, unless the Party has obtained the Producing Party's permission.

16. **FILING PROTECTED MATERIAL**

(a) Absent written permission from the Producing Party or a court Order secured after appropriate notice to all interested persons, a Receiving Party may not file or disclose in the public record any Protected Material.

(b) Any Party is authorized under District of Delaware Local Rule 5.1.3 to file under seal with the Court any brief, document or materials that are designated as Protected Material under this Order. However, nothing in this section shall in any way limit or detract from this Order's requirements as to Source Code.

17. **INADVERTENT DISCLOSURE OF PRIVILEGED MATERIAL**

(a) Pursuant to Federal Rule of Evidence 502(d) and (e), the inadvertent production by a Party of Discovery Material subject to the attorney-client privilege, work-product protection, or any other applicable privilege or protection, despite the Producing Party's reasonable efforts to prescreen such Discovery Material prior to production, will not waive the applicable privilege and/or protection in any other federal or state proceeding if a request for return of such inadvertently produced Discovery Material is made promptly after the Producing Party learns of its inadvertent production. For example, the mere production of a privileged or work product protected document in this case as part of a production is not itself a waiver. Nothing in this Order shall be interpreted to require disclosure of irrelevant information or relevant information protected by the attorney-client privilege, work product doctrine, or any other applicable privilege or immunity. The parties do not waive any objections as to the production, discoverability, admissibility, or confidentiality of documents and ESI. Moreover, nothing in this Order shall be interpreted to require disclosure of information subject to privacy protections as set forth in law or

regulation, including information that may need to be produced from outside of the United States and/or may be subject to foreign laws.

(b) Upon a request from any Producing Party who has inadvertently produced Discovery Material that it believes is privileged and/or protected, each Receiving Party shall immediately return such Protected Material or Discovery Material and all copies to the Producing Party, except for any pages containing privileged markings by the Receiving Party which shall instead be destroyed and certified as such by the Receiving Party to the Producing Party.

(c) Nothing herein shall prevent the Receiving Party from preparing a record for its own use containing the date, author, addresses, and topic of the inadvertently produced Discovery Material and such other information as is reasonably necessary to identify the Discovery Material and describe its nature to the Court in any motion to compel production of the Discovery Material.

18. **INADVERTENT FAILURE TO DESIGNATE PROPERLY**

(a) The inadvertent failure by a Producing Party to designate Discovery Material as Protected Material with one of the designations provided for under this Order shall not waive any such designation provided that the Producing Party notifies all Receiving Parties that such Discovery Material is protected under one of the categories of this Order within ten (10) days of the Producing Party learning of the inadvertent failure to designate. The Producing Party shall reproduce the Protected Material with the correct confidentiality designation within five (5) days upon its notification to the Receiving Parties. Upon receiving the Protected Material with the correct confidentiality designation, the Receiving Parties shall return or securely destroy, at the Producing Party's option, all Discovery Material that was not designated properly.

(b) A Receiving Party shall not be in breach of this Order for any use of such Discovery Material before the Receiving Party receives such notice that such Discovery Material

is protected under one of the categories of this Order, unless an objectively reasonable person would have realized that the Discovery Material should have been appropriately designated with a confidentiality designation under this Order. Once a Receiving Party has received notification of the correct confidentiality designation for the Protected Material with the correct confidentiality designation, the Receiving Party shall treat such Discovery Material (subject to the exception in Section 18(c) below) at the appropriately designated level pursuant to the terms of this Order.

(c) Notwithstanding the above, a subsequent designation of "CONFIDENTIAL," "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" shall apply on a going forward basis and shall not disqualify anyone who reviewed "CONFIDENTIAL," "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" materials while the materials were not marked "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" from engaging in the activities set forth in Section 6(b).

19. **INADVERTENT DISCLOSURE NOT AUTHORIZED BY ORDER**

(a) In the event of a disclosure of any Discovery Material pursuant to this Order to any person or persons not authorized to receive such disclosure under this Protective Order, the Party responsible for having made such disclosure, and each Party with knowledge thereof, shall immediately notify counsel for the Producing Party whose Discovery Material has been disclosed and provide to such counsel all known relevant information concerning the nature and circumstances of the disclosure. The responsible disclosing Party shall also promptly take all reasonable measures to retrieve the improperly disclosed Discovery Material and to ensure that no further or greater unauthorized disclosure and/or use thereof is made.

(b) Unauthorized or inadvertent disclosure does not change the status of Discovery Material or waive the right to hold the disclosed document or information as Protected.

20. **FINAL DISPOSITION**

(a) Not later than ninety (90) days after the Final Disposition of these cases, each Party shall return all Discovery Material of a Producing Party to the respective Outside Counsel of the Producing Party or destroy such Material, at the option of the Producing Party. For purposes of this Order, "Final Disposition" occurs after an order, mandate, or dismissal finally terminating these cases with prejudice, including all appeals.

(b) All Parties that have received any such Discovery Material shall certify in writing that all such materials have been returned to the respective Outside Counsel of the Producing Party or destroyed. Notwithstanding the provisions for return of Discovery Material, Outside Counsel may retain one set of pleadings, correspondence and attorney and consultant work product (but not document productions) for archival purposes, but must return any pleadings, correspondence, and consultant work product that contain Source Code.

21. **MISCELLANEOUS**

(a) Right to Further Relief. Nothing in this Order abridges the right of any person to seek its modification by the Court in the future. By stipulating to this Order, the Parties do not waive the right to argue that certain material may require additional or different confidentiality protections than those set forth herein.

(b) Termination of Matters and Retention of Jurisdiction. The Parties agree that the terms of this Protective Order shall survive and remain in effect after the Final Determination of the above-captioned matters. The Court shall retain jurisdiction after Final Determination of these matters to hear and resolve any disputes arising out of this Protective Order.

(c) Successors. This Order shall be binding upon the Parties hereto, their successors, and anyone, including law firms, who obtains access to Protected Material.

(d) Right to Assert Other Objections. By stipulating to the entry of this Protective Order, no Party waives any right it otherwise would have to object to disclosing or producing any information or item. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Protective Order. This Order shall not constitute a waiver of the right of any Party to claim in these cases or otherwise that any Discovery Material, or any portion thereof, is privileged or otherwise non-discoverable, or is not admissible in evidence in these cases or any other proceeding.

(e) Modification by Court. This Order is subject to further court order based upon public policy or other considerations, and the Court may modify this Order *sua sponte* in the interests of justice. The United States District Court for the District of Delaware is responsible for the interpretation and enforcement of this Order. All disputes concerning Protected Material, however designated, produced under the protection of this Order shall be resolved by the United States District Court for the District of Delaware.

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Dated: June 14, 2023

IT IS SO ORDERED this 16th day of June, 2023.

The Honorable Jennifer L. Hall
United States District Court Magistrate Judge

EXHIBIT A

I, _____, acknowledge and declare that I have received a copy of the Protective Order ("Order") in *Apple Inc. v. Masimo Corp. et al.*, United States District Court, District of Delaware, C.A. Nos. 22-1377-MN-JLH and 22-1378-MN-JLH. Having read and understood the terms of the Order, I agree to be bound by the terms of the Order and consent to the jurisdiction of said Court for the purpose of any proceeding to enforce the terms of the Order.

Name of individual: _____

Present occupation/job description: _____

_____

_____

Name of Company or Firm: _____

Address: _____

Dated: _____

_____

[Signature]

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